NRC/INEL Radiation Therapy Event Investigation Team Report 9501

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ACRONYMS

CCTV	closed circuit television
CFR	code of federal regulations
Gy	gray
INEL	Idaho National Engineering Laboratory
ISO	International Organization for Standardization
mrem	millirem
MRI	nuclear magnetic resonance imaging
NRC	United States Nuclear Regulatory Commission
QM	quality management
QMP	quality management plan

NRC/INEL RADIATION THERAPY EVENT INVESTIGATION TEAM REPORT 9501

INTRODUCTION

Purpose

The Nuclear Regulatory Commission (NRC) amended its regulations in 10 CFR 35 concerning the medical use of by-product material[1] to require medical licensees to establish and implement a quality management program (QMP). This rule was to be implemented by January 27, 1992. The overall goal of the QMP is to prevent errors in the medical use of by-product material.

This report is the result of an investigation by a team contracted by the NRC to review radiation therapy events. The purpose of this team is to obtain the necessary detailed information on selected events and perform an analysis of the causes, contributing factors, risk significance, and corrective actions.

Normally, the NRC obtains this information to help it evaluate the adequacy of the scope and depth of the QM rule.

Scope

The team investigation is limited to the administration of the prescribed radiation treatment. The team members review the facts of the event and compare them to the facility's normal process and the NRC's regulations.

The team members are tasked to describe the events, compare them to the requirements, analyze for the cause of the event and contributing factors, assess the risk significance, and describe and evaluate the licensee response.

The amount, type, and modality of radiation originally prescribed are medical matters and, as such, is outside the scope of this investigation.

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1 Byproduct material means--

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

EVENT DESCRIPTION

Overview

A two-position, solenoid-operated valve on the hydraulic system of a gamma knife unit failed during a recent treatment. The valve (valve 20) that failed controls the direction of bed movement. The valve was inspected by personnel from Elekta Instruments, Inc., the U.S. distributor of the gamma knife, and then sent to the valve manufacturer for analysis. Elekta has attributed the failure to a particle of metal that either caught between the valve spool and valve body or scored the spool, in either case essentially locking the valve in the 'bed in' position. The behavior of the device and the system response when valve 20 was replaced leave no doubt that a malfunction of this valve precipitated the event.

A report from the manufacturer on the failed valve is pending. Although a metal particle that may have caused the failure was not found by Elekta or the valve manufacturer, the valve spool is scored. This evidence supports the theory that a metal particle damaged or jammed the valve.

System Description

The gamma knife is a device used to deliver a high dose of radiation to a small location in the interior of a patient's head, while keeping the radiation dose delivered to the rest of the head and body as low as possible. It does this by collimating hundreds of radioactive sources in a hemispherical mount so that the resultant radiation beams intersect at an isocenter and yield a high dose volume between a fraction of a cubic centimeter (cc) and a few cc, depending on which collimator helmet is used. Outside the isocenter region, the radiation dose diminishes rapidly because there is minimal overlap of the radiation beams. The patient is precisely placed

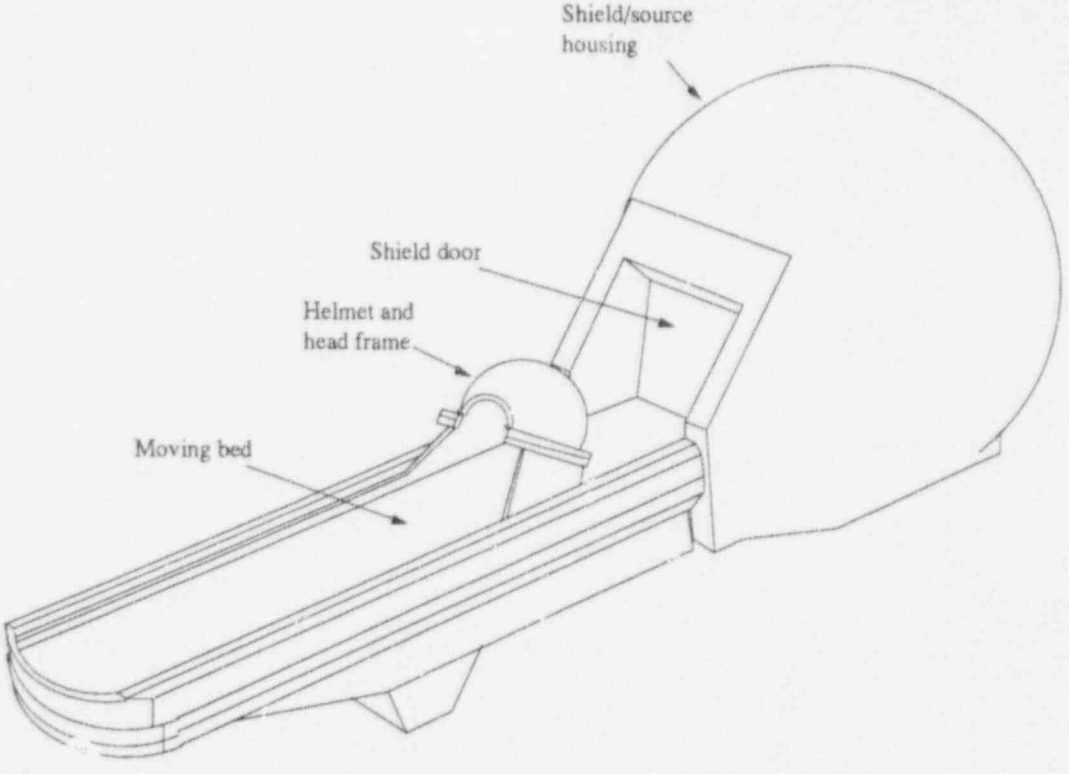


Figure 1: Line drawing of gamma-knife

in the radiation chamber for a controlled time to accomplish the treatment. Individual beams may be blocked to shape the high dose region to some degree.

The gamma-knife's sources are located in the shield/source housing (See Figure 1) and are collimated to form an isocenter near its center. The bed moves into and out of the "face opening" of the housing. A hydraulically operated door is shut when the machine is idle to provide shielding and security.

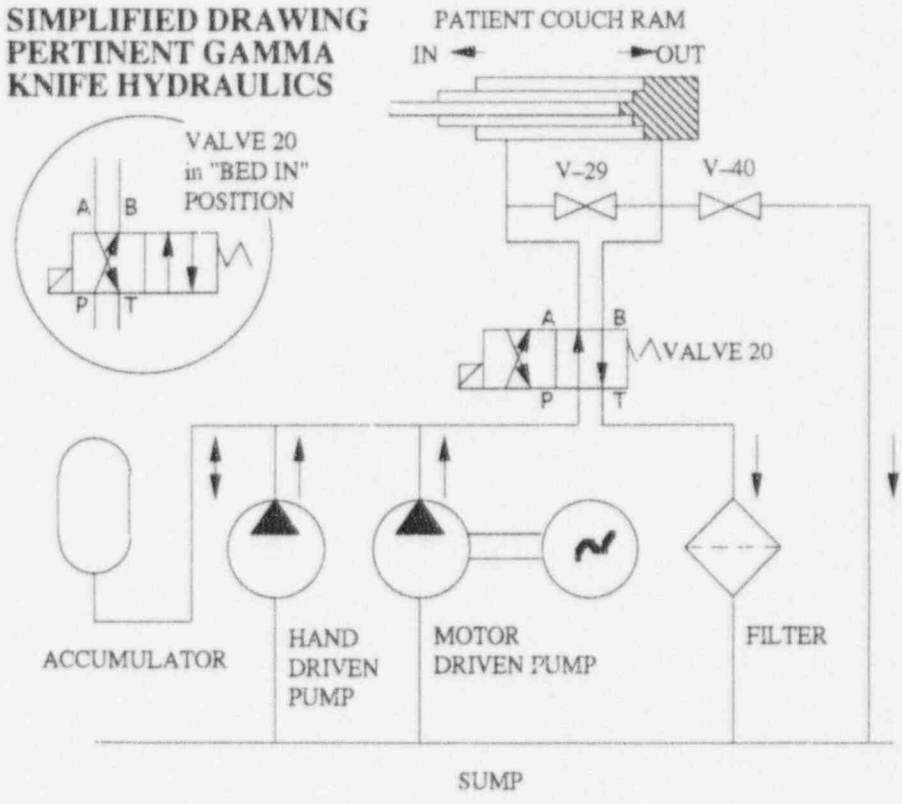


Figure 2. Simplified Hydraulic Schematic

To perform a treatment "shot" the patient is first positioned within a helmet on the moving bed and the patient's head is fixed in a well-defined position relative to the helmet using a headframe that is mounted on trunnions. To start the exposure, the device opens the shield door and hydraulically inserts the helmet and bed, with the patient, into the radiation chamber, thus placing the target region of the head coincident with the radiation isocenter of the gamma knife. The shot is ended when the bed is hydraulically removed from the radiation chamber and the shield door is shut. A typical treatment requires multiple shots to cover the entire target area with the patient's head being repositioned between each shot. Tabulation of over 400 treatments conducted at the University of California, San Francisco resulted in a mean of 6.96, a median of 7, and a range 1 to 21 for the number of shots in a treatment.

Detailed Description

The responses of the gamma knife device during the incident confirm that valve 20 was stuck in the 'bed in' position. The events that occurred during the incident and the corresponding status or reactions of the hydraulic system are listed in Table 1.

Table 1. Hydraulic System Explanation of Events

	Event	Hydraulic System Explanation
1	The bed failed to retract when the treatment time was completed after the sixth exposure cycle.	Valve 20 was stuck in the 'bed in' position. Hydraulic pressure applied by the system to remove the bed was instead directed by valve 20 to insert the bed.
2	The 'patient out' lamp was flashing, but the bed was not moving.	The solenoid that controlled valve 20's spool position had properly deenergized, which would normally allow the valve to return to the position that retracts the bed. The return spring could not move valve 20's spool, however, because of a suspected particle caught between the spool and valve body or spool damage.
3	The sound of the hydraulic pump was heard, but there was no movement of the bed.	The pump was continuing to send fluid to valve 20, as it would during normal retraction of the bed. (See item 1)
4	Manual pumping did not cause the bed to move.	The manual pump supplies system hydraulic pressure. But the pump and accumulator were functioning properly and there was sufficient pressure. The problem was that the pressure was misdirected.
5	The 'treatment off' button was pushed on the control console, but the bed did not move.	Valve 20's spool was still stuck, and its internal spring could not reset it. Under normal conditions, this action would turn the pump on and direct the pressure to remove the bed.
6	Two facility staff members entered the treatment room, released the latch at the foot of the bed, and were able to pull the bed a small distance. Moving the bed was very difficult.	The latch is attached to two manual valves—valves 29 and 40 on figure 2—that equalize the hydraulic system pressure on the bed ram and allow limited manual movement of the bed. While in this mode, bed movement is limited because hydraulic fluid must be forced from one side of the bed ram, through the bypass valve and a cut off valve, to the other side of the ram as the bed moves.
7	Three facility staff members again pulled on the bed. The bed moved an estimated 50 cm, still with difficulty.	As before, movement of the bed manually was possible, but difficult.
8	A "locking sound" was heard and the bed could not be moved any further. At this point, the staff followed emergency procedures to remove the patient from the helmet.	The INEL team does not attribute the "locking sound" to the hydraulic system. It is not clear where the noise originated, but it appears to have been due to metal-on-metal contact of the bed wheel with its track where the slope of the track changes. This event does not appear to be significant from a hydraulics standpoint.
9	After the patient was removed, the latch was pushed back into normal position.	The valves allowing the bed to be moved manually (valves 29, 40) were closed. If the accumulator had still been pressurized, this action would have caused the bed to move back into the unit. However, while the manual bypass valves were open the accumulator had depressurized to the sump.

	Event	Hydraulic System Explanation
10	The 'treatment off' button was pushed on the console. The bed moved from its partially retracted position back into the unit, instead of retracting.	Pushing the 'treatment off' button turned the pump back on. The pump then returned the system to the pressure needed to move the bed. Since valve 20 was still stuck in the 'bed in' position, the bed moved back into the unit.
11	The console key was turned off, but again did not result in retraction of the bed, as expected.	In normal operation, turning off the console key retracts the bed because, without power, the valve spools move to positions that, with the remaining pressure in the accumulator, cause the bed to retract. Again, the bed valve 20 could not return to its relaxed position, and therefore the bed could not return to the retracted position.

MITIGATION AND MEDICAL CONSEQUENCES

Physics Overview

Although it is not explicitly stated in the incident memorandum, the most likely conclusion is that when the facility staff first released the latch at the foot of the table, the helmet with the patient dropped from its highest position, where it was mated with the primary collimator, to the lowest position corresponding to the low point of the couch track.

A previous study[2] determined that this results in a high dose volume approximately 2 cm in diameter located just under the inner surface of the top of the helmet and substantially superior to the treatment position. Based on the coordinates of the shot and the skull measurements for this patient, it is calculated that the top of the head was 4 cm below the inner surface of the helmet. This places the high dose volume outside the patient.

The high dose volume would lie inside the head of the patient if the helmet had stopped at some point intermediate between the treatment position and the low point, but it is not likely that this happened. It is of note that when the helmet is at the low point, the maximum dose rate at the focus of the primary collimator through the helmet is approximately 10% of the dose rate at the treatment position because of the lack of alignment with the helmet openings. It should also be noted that under these circumstances although the beams would have come to a focus at a point outside the patient, the beams would have continued beyond this focus and some of them may have partially intersected the patient. However additional dose due to this process would have been small compared to the prescribed and delivered doses.

Assuming that the helmet did drop to the lowest point, the team are in agreement with the comments and conclusions of the facility staff. The physicist's assessment regarding additional radiation and volume affected is given below.

Treatment

For this evaluation the volume of the target was estimated as follows. The target was drawn on the coronal MR images by the facility neuroradiologist. The Gammaplan computer software is able to calculate volumes from axial images but not from coronal images. The program was used to project the target contours from the coronal images on to the axial images, and then to draw new target contours on the axial images based on the coronal projections. This procedure yields a target volume which may not exactly correspond with the tumor but which should be accurate enough to give a relative comparison between the original and delivered treatment volumes. Such a comparison is useful in allowing the effect of the inadvertent irradiation to be put into perspective. For these comparisons it was assumed that the four shots which were not delivered when the incident occurred have subsequently been delivered with the same parameters as per the original plan.

Original Plan

The plan was designed to deliver a prescribed dose of 15 Gy to the 45% isodose surface which adequately covered the target. Three 14 mm shots and seven 8 mm shots were to be used. Shot five[3], which was an 8 mm shot, was to have been treated for 3.35 minutes. It is calculated that the volume enclosed by the 45% isodose surface was 5.4 *cc* (in agreement with facility staff), that the target volume was 4.5 *cc*, and that the partial volume of the target within

2 Smith, V.; Verhey, L.; Jones, E.; Lyman, J. Consequences to the patient in the event of hydraulic unit failure. Stereotactic & Functional Neurosurgery. 61(Supplement 1):173-7; 1993.

3 Shots are not necessarily performed in the same order they are listed in the plan. In this case shot number 5 (the fifth shot calculated on the plan) was the sixth shot to be performed during the treatment.

the 45% isodose surface was 4.0 *cc*. This means that 1.4 *cc* (5.4*cc* − 4.0*cc*) of normal tissue was also included in the 45% isodose surface of the original plan.

Delivered Treatment

All shots were the same as for the original plan except that shot 5 was treated for a time of 7.13 minutes. The volume enclosed by the 45% isodose surface was 6.0 *cc*, the target volume was still 4.5 *cc*, and the partial volume of the target within the 45% isodose surface was 4.2 *cc*. This means that 1.8 *cc* (6.0*cc* − 4.2*cc*) of normal tissue was also included in the 45% isodose surface.

Physics Conclusion

The following physics opinion provided by Dr. Vernon Smith is based on copies of materials provided by INEL, by the institutional radiation safety officer, and by an independent medical physicist.

Comparison of the original and delivered plans indicates the following:

- The volume enclosed within the 45% isodose surface increased by 0.6 *cc* from 5.4 *cc* to 6.0 *cc*, or 11%.
- The volume of the target enclosed by the 45% isodose increased from 4.0 *cc* to 4.2 *cc*. To put it another way, the percentage of the target enclosed within the prescription isodose increased from 89% (4.0*cc*/4.5*cc*) to 93% (4.2*cc*/4.5*cc*). This in itself should be of benefit to the patient.
- The volume of normal tissue enclosed within the 45% isodose increased from 1.4 *cc* to 1.8 *cc*.

Thus we have a negative effect (an increase in the volume of normal tissue receiving a significant dose) and a positive effect (an increase in the percentage of the target receiving the prescribed dose). However both effects are quite small and probably do not significantly affect the treatment. It could be argued that the differences between the original and delivered plans are within the range of the differences seen between one institution and another, or between one clinician and another, and both could be judged to be acceptable plans.

Medical Effects

The following medical opinion provided by Dr. David Larson is based on copies of materials provided by INEL, by the institutional radiation safety officer, by an independent medical physicist, and by Dr. Vernon Smith.

Effect to Patient

The volume of normal tissue enclosed within the prescription isodose surface increased by less than half a cubic centimeter. This should be of negligible clinical consequence, since the increased normal tissue volume does not appear to contain critical normal structures such as optic nerves or chiasm or other cranial nerves, or critical small blood vessels, or critical neural tissue.

The volume of the target enclosed by the prescription isodose surface increased by approximately 0.2 *cc*, and may result in slightly reduced risk for tumor regrowth.

Further from the target volume, where the dose has dropped off to the 20% level, changes in the isodose contour are minor and of no clinical significance. Beyond that, changes in lower isodose surfaces are of no clinical consequence.

In summary, regarding dose to the patient, differences between the original and delivered treatment plans are small compared to much larger differences in doses prescribed by different institutions for pituitary tumors. The maximum dose delivered to the patient in question was approximately 33.5 Gy, compared to a planned dose of 33.33 Gy. Some experienced Gamma Knife radiosurgeons would have selected a maximum dose of only 20–25 Gy, whereas others would have selected a maximum dose of up to 40 Gy. This range of maximum doses is considered within the range of acceptable practice standards. In addition, other radiosurgeons might have drawn a target volume that differed by several millimeters in any diameter from that which was used on the patient in question. Such target volume variations are also within the range of acceptable practice standards, and reflect the inability of MRI to pre-

cisely delineate where microscopic or even gross volumes of tumor cells reside.

Effect to Clinical Staff

It appears the medical staff all received less than 3 mrem. This exposure is probably insignificant, since it approximates the negligible individual risk level, the level of excess risk of total health effects below which further efforts to reduce radiation exposure are unwarranted. (A risk of 10^{-7} per year corresponds to an annual effective dose equivalent of 1 mrem.) The exposure to medical staff is very small compared to the annual average total effective dose equivalence to the U.S. population of approximately 650 mrems (including natural background of approximately 300 mrems). It is not known whether any of the medical staff may have been pregnant at the time of the equipment failure or whether such personnel may have received any exposure at the time of the equipment failure. However, with the exception of the badge reading of the (male) medical physicist (whose badge was left on the treatment room floor overnight), all personnel badge readings appear to be extremely low compared to the recommended maximum permissible monthly dose to embryo and fetus of 50 mrem. In summary, the medical effects of the equipment failure to medical personnel (and possible embryos and fetuses) are probably negligible.

CORRECTIVE ACTIONS

The corrective actions taken by Elekta include the instructions given to facility staff on the day the incident occurred, repairs by an Elekta engineer the next day, and planned actions to prevent a future occurrence of the incident.

Immediate

Facility physicists phoned Elekta after removing the patient from the device but could only reach the answering service due to the time of day (8:45 PM EST in Georgia, where Elekta offices are located). When the Elekta engineer returned the telephone call at 9:07 PM EST, his advice was to turn the console off, leave it off, and he would come to the facility the next day.

Short-Term

Upon arrival at the facility, the Elekta engineer informed the staff that it appeared the valve that controls bed position was mechanically stuck. He performed limited testing to verify his hypothesis and check on alternative ones. After determining his hypothesis was correct, he replaced valve 20. This repaired the unit. He then ran several tests of the bed to confirm that the repair was adequate. The engineer then certified the equipment for clinical use.

Long-Term

To address this event, Elekta is testing the placement of 75µm screens between the hoses to the treatment room and the valves in the hydraulic room at a separate facility. These screens would prevent any particles greater than 75µm that may be in the hoses or rams from reaching the solenoid valves that control bed and door positions.

With this solution, any particles that may be in the system between the screens would not be removed from the system. Rather, these particles would travel between the applicable screens and hydraulic ram cylinders each time the unit cycles. The Elekta engineer who repaired the unit stated that the rams have larger clearances than the position control valves in the hydraulic room and would not be affected by particles in the fluid.

In addition to the rams, there are also two valves (one each on the bed and door subsystems) between the screens that the particles could typically travel through, and two more in the bed subsystem that could be involved in an emergency. The Elekta engineer stated that the clearances were large enough in these valves that they also should not be effected by particle contamination.

Evaluation

Evaluation of the corrective actions is presented in the engineering conclusions of this report.

CONCLUSIONS

Proximate Cause

The cause of the Gamma Knife failure was the existence of metal contaminants in the hydraulic fluid system, believed to have been introduced during installation, several months previously.

The contaminants caused valve 20 to jam in the 'bed in' position.

Medical

Differences between the original and delivered treatment plans are small compared to much larger differences in doses prescribed by different institutions for pituitary tumors.

The medical effects of the equipment failure to medical personnel (and possible embryos and fetuses) are probably negligible.

Engineering

The cause of the malfunction of the gamma knife device is hydraulic fluid contamination. Hydraulic systems are characteristically very reliable; fluid contamination is the primary cause of failures (both direct and indirect). Although Elekta takes precautions while installing a new device to prevent the introduction of contaminants into the system, such as cleaning the hydraulic hoses before installation, it is apparent that in this case these precautions were not enough.

It is Elekta and the INEL team's conclusion that during installation, the pieces of dirt, metal, and rubber that are typically found in new hydraulic hoses were not properly cleaned from one of the hoses. Pieces of rubber found by Elekta in the hydraulic fluid filter support this theory.

Most of this contamination traveled through the system without incident, and was filtered from the fluid before reaching the reservoir. The metal particle that caused valve 20 to fail may have remained trapped in the system or connected to the parent metal fitting until it worked loose after many machine cycles. This theory would explain why the device failed after being tested and run several times.

Evaluation of Corrective Actions

The immediate actions by Elekta and the on-site repair performed the next day are considered appropriate and will not be analyzed further. This section presents a more detailed analysis of the contaminants in the system and the solution proposed by Elekta to prevent reoccurrence of this problem.

Oil and Filter Analysis

In order to verify the source of contamination it is important to determine if the contaminants are copper, steel, rubber, or other material. Once the composition of the contaminants is known and the source identified, the likely path may be determined. In addition to a human error when installing the device (such as improperly cleaning a hose), other possible explanations include an undetected equipment or hose defect, or contamination in valves, rams, or the fluid reservoir.

A visual inspection of the oil and filter will not always show a contamination problem, since much of the contamination that will impair a hydraulic system is smaller than 40µm—the limit of visibility of the human eye.

Filter size

The screens installed between the hydraulic manifold and the operating rams in a similar unit are 75µm filters. For the solenoid valves in this system, a filter size of 15–20µm is appropriate. While it is not known how large the particle that caused this event was, it is true that a particle small enough to fit through a 75µm screen could cause a similar valve malfunction. Thus, these screens will prevent a similar event in the future only if the particles are large. The INEL team therefore considers the placement of 75µm screens as a long-term corrective action to be marginally effective.

Risk Analysis

Other single failures

The system was analyzed for its potential for other single component malfunctions that might cause unintended radiation exposure to the patient.

The system contains nine key components, each with at least two modes, and has nine unique system states. The number of possible failures and the consequences of each during the different stages of the operation make a full analysis of these failures outside the scope of this report.

To limit the scope of the analysis, it was assumed that the device worked properly through the insertion of the bed and the start of the radiation treatment. The justification for this assumption is that any malfunction that occurs prior to inserting the patient into the radiation chamber allows the staff to stop the process before irradiation begins, thus preventing unintended radiation to the patient. Similarly, states that occurred after the patient was properly removed from the radiation chamber, such as shutting the shield door, were not considered because they did not contribute additional radiation to the patient.

Thus, only single component failures that could occur during the irradiation phase and bed withdrawal phase of the operation were examined and only single component failures were considered. Loss of power during the irradiation was also considered. The results of the analysis are summarized below in Tables 2–4. Failures that had no effect are not listed. Incredible failures were not included.

There are only three basic failures that can be caused by a valve positioning incorrectly that affect the bed movement: either the bed will not move into the unit, the bed retracts from the unit at the incorrect time, or the bed fails to retract when it should. Only the valve malfunctions that prevent the bed from retracting could result in an increased treatment time for the patient. These are the only failures considered.

Table 2: State: Hold bed in treatment position

Case No.	Failed Component	Failure Position*	Effect	Unintended Irradiation
1	Valve 19	fails on	bed drifts out of position, which causes the treatment to be automatically stopped, but patient must be withdrawn manually	Possible
2	Valve 20	fails on	bed retracts from the unit	no
3	Valve 22	fails on	bed drifts out of position, which causes the treatment to be automatically stopped, but patient must be withdrawn manually	Possible
4	Valve 36	fails on	bed drifts out of position, which causes the treatment to be automatically stopped, and patient and bed are hydraulically withdrawn	no
5	Valve 38	fails off	bed speed rises	no

*The positions listed refer to the condition of the valve under normal operation when the solenoid is "on" or "off".

Table 3: State: Withdraw bed

Case Nr	Failed Component	Failure Position*	Effect	Unintended Irradiation
6	Valve 19	fails on	bed fails to move out of the unit, patient must be removed manually	YES
7	Valve 20	fails on	bed fails to move out of the unit, patient must be removed manually	YES
8	Valve 22	fails on	bed fails to move out of the unit, patient must be removed manually	YES
9	Valve 38	fails off	bed speed rises	no
10	Pump	fails off	bed speed rises	no

*The positions listed refer to the condition of the valve under normal operation when the solenoid is "on" or "off".

Table 4: State: Loss of power during treatment

Case Nr	Failed Component	Failure Position*	Effect	Unintended Irradiation
11	Valve 20	fails on	bed fails to move out of the unit	YES
12	Valve 36	fails on	bed fails to move out of the unit	YES

*The positions listed refer to the condition of the valve under normal operation when the solenoid is "on" or "off".

Failure Frequency

Without detailed analysis, the frequency of recurrence of failures that cause unintended radiation to the patient can only be evaluated qualitatively.

Given that the cause of this failure appears to be related to device installation, the following conclusions can be made.

This appears to be an "infant mortality" type failure—it is dependent on the number of installations and inversely proportional to the number of cycles (age) completed by the machine.

Other machines that were installed before and have been cycled more than the machine in this study are less likely to have a similar failure; however, this type of failure remains a concern for the installation of new machines.

It should be noted that this failure occurred on the sixth cycle of a ten-cycle treatment. Treatments are seen to range from one to 21 shots. As more shots are performed in rapid succession, any debris that is settled in the sump tank will be mixed by the returning hydraulic fluid and will have a relatively higher likelihood of being drawn into the system on the next cycle as the number of cycles rises.

Consequences

See *Mitigation and Medical Consequences* above.

Risks

One of the valve positioning malfunctions analyzed—case 7 in Table 3—occurred in the event this report examines. Because this event represents a worst-case solenoid-operated valve failure and has a small likelihood of occurring at other, older facilities; and because its medical effect was probably negligible; we conclude that the risk significance from this type of failure is very small for future gamma knife usage *provided the staff responds correctly.*

RECOMMENDATIONS

Engineering Recommendations

Oil and Filter Analysis

A laboratory analysis of the hydraulic fluid and the filter is recommended to determine the level and type of contamination in the system. An oil sample and filter sample should be taken for laboratory analysis during the next scheduled preventative maintenance of the facility unit, January 10, 1995. (This was discussed with Elekta technical staff prior to this report's completion.)

Information on the type, the sizes, and the amount of contamination present would be provided by an analysis of the hydraulic fluid by an oil analysis laboratory. Oil analyses are routine for many hydraulic systems and engines. A local oil analysis company should be contacted before taking a sample to ensure the proper procedures are followed. The sample must be representative of the entire fluid. The filter on the reservoir should also be analyzed for larger particles. The International Organization for Standardization (ISO) code for the sample and filter oil, the types of contaminants and their approximate shapes (if possible) should be requested from the laboratory.

The results of the oil analysis should be reviewed by this team to ensure the assumptions about the contamination levels in this evaluation are correct. It is also recommended that oil samples from at least five other gamma knives installed in the U.S. are analyzed and reviewed. As a final preventative measure, it is recommended that for all new units installed in the U.S. in the future, an oil sample is analyzed after the device testing is completed and before certification. This is a relatively easy and inexpensive procedure.

If Elekta plans to modify all units in the U.S., as they have stated, these analyses should be performed before modifications are started, in case the results do not support the previous conclusions.

Filter Configuration

To further reduce the possibility of a repeat failure of the kind experienced at the facility, a modification of Elekta's planned design change is recommended. This design change must be verified by Elekta to ensure the pressure drops across the new filters do not interfere with correct operation of the unit.

A simplified schematic of the modification of the bed positioning portion of the hydraulic system as proposed by Elekta is shown in Figure 3. The schematic for the door positioning portion of the system is very similar, and is not shown. In the diagram shown, fluid is pumped through the valve and the left screen to the left side of the ram cylinder. The fluid on the right side of the ram cylinder is pushed through the right screen, then through the valve and to the reservoir. When the solenoid is energized, the valve spool moves into the other position (where the lines are shown crossed). The fluid from the pump then leaves the valve on the right side and flows from the right screen to the right side of the ram cylinder. The fluid in the left side of the ram cylinder is forced down through the left screen, through the valve and to the reservoir.

There are two problems with this proposed solution. First, 75 µm is not be an adequate filter size for these valves. Second, instead of removing any contaminants from the system, the contaminants stopped by the screens will travel back and forth between the screens and the ram cylinders. The probability that particles (especially metal slivers) will eventually travel through one of the screens to the bed or door position valve is increased each time the fluid flow changes direction and particles are released from the screen.

Figure 4 shows the recommended solution for filtering the fluid. Filters are used instead of screens to remove contaminants from the system, instead of allowing them to travel from one screen to the other through the ram cylinder. Hydraulic systems typically use 10–25 µm filters, depending on the level of cleanliness required. Twenty µm filters were chosen based on discussions with a representative of the manufacturer of valve 20. This filter size is also used by the manufacturer of the gamma knife on the return line to the reservoir.

When the control valve is in the position shown, fluid flows from the pump, through the control valve into the left side of the system, through the check valve in the left side bypass, and to the left side of the ram cylinder. The fluid in the right side of the ram cylinder is pushed through the right side of the system and through the filter on the right. The check valve on the right bypass prevents the exiting flow from bypassing the right filter. The fluid then passes through the control valve and returns to the reservoir. When the control valve is put in the other position, the incoming fluid bypasses the right hand filter and the exiting fluid is forced through the left filter. The check valves at the exit of the filters will prevent backflow through the filters.

Valve Access

If the remote manual operator for valves 29 and 40 becomes disconnected from either valve, there is potential for unplanned exposure at the treatment rate until the patient is physically removed using the special tools to disengage the headframe from the trunnions. The removal in this case is expected to take longer because the bed and helmet assembly are farther inside the treatment unit.

The connectors on the remote manual operator for these valves were inaccessible to this team, and were not inspected. No opinion can be given to the likelihood of their failure.

If the remote manual operator became disconnected, an access panel in the bed foundation above valves 29 and 40 might allow the staff to open these valves directly and lower the bed from the treatment position before starting to disengage the trunnions

Tools

All gamma knife facilities should obtain the second emergency tool—the long handled pry bar for disengaging the head frame from the trunnion.

Operating Procedures

As discussed above, the relative likelihood of a similar event recurring is larger at the end of a multi-shot treatment than at the start of that treatment. Consequence of a recurrence, and therefore the risk of a recurrence, can be reduced by performing the large aperture shots first and the small aperture shots last. Then, given that a malfunction does occur during a treatment, the conditional probability that it will occur during a large aperture shot will have been minimized and the affected volume will be smaller.

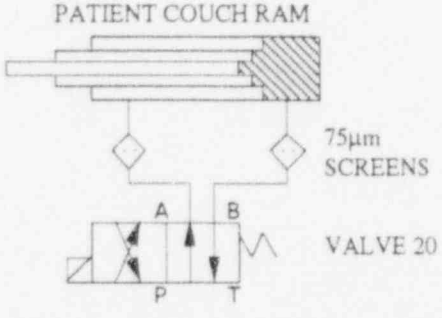


Figure 3. Elekta's Proposed Solution

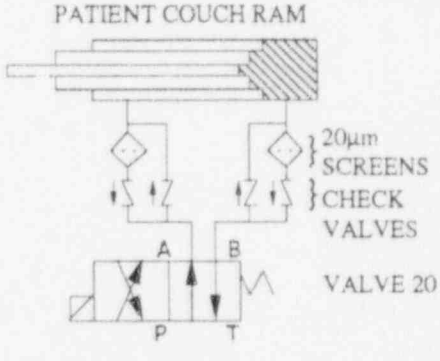


Figure 4. Recommended Solution

Emergency Procedures

All gamma knife facilities should review their emergency procedures to ensure they cover the following points in the event the bed fails to retract: if the power is on, the hydraulic pressure is within range, but the treatment bed fails to retract after the timer reaches 0.00, move on to the emergency procedures for releasing the patient from fixation in the helmet. This change was made to the emergency procedures of the facility where the incident occurred by the staff involved.

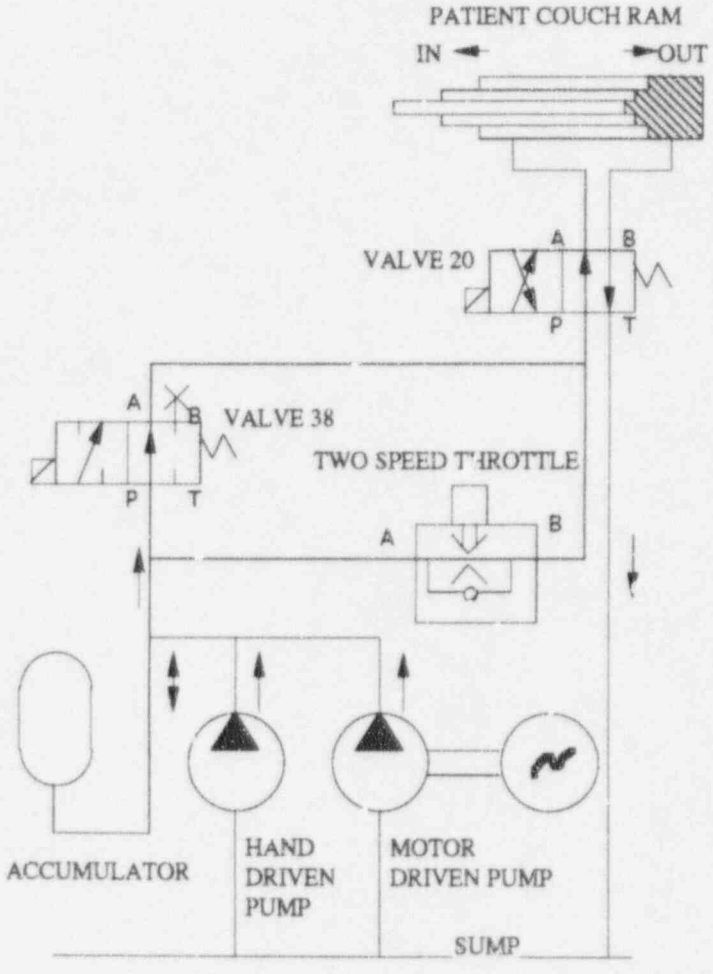
Training

All gamma knife facilities should hold a staff review and walk through of their emergency procedures. Operating staff should dismount the head cage from the trunnions using the long handled wrench and lever provided for emergencies. This can be done with the door shut and the bed in the fully retracted position.

Video Tape

As with most investigations, reconstruction of important details was difficult. It is recommended that a VCR or similar recorder be connected to the CCTV and the treatments be recorded. Once a treatment is completed without incident, the tape may be reused for the next treatment. If there is a problem, the tape can help determine specific durations, bed movements, and sequences during the review of the emergency response. To aid in determining bed movement, a graduated color bar or series of lines could be affixed to the bed foundation below the bed.

Apparent Inconsistency



When Stephanie Walker and I reviewed the electrical schematics for the control logic we found an inconsistency. The inconsistency pertains to the operation of hydraulic valve 38. Although, physically, this valve closely resembles the other hydraulic valve; operationally it is connected so that it may be thought of as a simple "open or shut" valve. Valve 38 is on a bypass line around the two-position, speed-control throttle valve on the bed supply line. When valve 38 is open, as shown in the diagram, the fluid will avoid the constriction of the two position throttle valve and flow through the bypass line. The bed will then move in or out of the treatment position more quickly.

Under all normal equipment operating conditions the solenoid is energized and the valve is "shut." On the loss of power the solenoid on valve 38 will be deenergized and the valve will allow hydraulic fluid to bypass the throttle valve. This allows the reserve fluid in the accumulator to move the bed out of the treatment position more quickly than would otherwise be possible.

It appears that this is intended to more quickly remove the patient during a situation when the accumulator or hand-driven pump are the only pressure sources.

From the electrical schematics, we also observe that if the power breaker to the motor-driven pump opens while control power remains to the rest of the system, then the treatment will complete its programmed time. Then the system will withdraw the bed on the accumulator (or hand-driven pump) pressure. The control circuit schematics show that in this case valve 38 remains shut.

If the assumption is true that the purpose of valve 38 is to allow faster retrieval of the bed when only the accumulator or hand-driven pump is available as a fluid source, then it is inconsistent that valve 38 does not open when the pump-motor breaker opens.

We do not claim that this is unsafe, we only point out what appears, with our limited review, to be an inconsistency in the control logic.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 27, 1995

Thomas E. Hill, Manager
Radioactive Materials Program
Department of Natural Resources
4244 International Parkway, Suite 114
Atlanta, GA 30354

Dear Mr. Hill:

This is in further response to your November 1, 1994 letter requesting technical assistance on evaluation of the gamma knife device failure.

Enclosed is the final report from our contractor, the Idaho National Engineering Laboratory (INEL) which we previously discussed with you by telephone. Also enclosed, is a letter from INEL expressing concern regarding an electrical circuit that was also identified during their evaluation.

We would appreciate your sending a copy of both the report and the letter to Elekta Instruments, Inc. and we welcome any comments you or they may have.

Sincerely,

Paul H. Lohaus, Deputy Director
Office of State Programs

Enclosures:
As stated