


# Memo

To: Radiological Devices Panel, Medical Devices Advisory Committee, Food and Drug Administration  
From: Michael Plasmeier  
362 Memorial Drive  
Cambridge, MA 02139  
Date: 2/13/2012  
Re: Therac-25 Investigation



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## Requiring Logging will help in the Investigation of Future Accidents

Thank you for the opportunity to comment on the investigation into the Therac-25 accident.

In order to help the investigation of future accidents, the FDA should require that new radiological medical devices log all physical operations of the machine.

All physical operations should include all mechanical operations and all radiological events. In addition, the machine should log all of the parameters of a particular operation. These parameters may sometimes be collectively referred to as the “treatment plan.” The machine should record the output of all sensors before and after mechanical operations. For radiological events, the machine should record the output of all sensors continuously during such operations.

For example, if the operator instructs the machine to rotate the turntable, that command, including the desired position of the turntable should be recorded. The machine should also record the output of the encoder on the turntable before and after the operation. If the operator instructs the machine to engage, that command, along with all parameters (the “treatment plan”) should be recorded. While the machine remains engaged, the data from all sensors should be logged.

These logs should be stored in a tamper-evident storage system which automatically retains all logs for 2 weeks.

“Black boxes” have proven invaluable helpful in the investigation of transportation accidents. Since their introduction in the 1960s, “black boxes” have proven invaluable in the investigation of accidents of aircraft, trains, automobiles, and ships. These data loggers help investigators rewind the steps leading up to the accident, allowing the cause of an accident to be determined. By understanding the cause of an accident, regulators can help make sure that the incident does not reoccur. The FDA should add similar logging to all radiological devices.