

no specifications or procedures for assembling the excimer laser devices. He said that he did not keep any written procedures for assembling the devices. He stated that the design specifications were all done verbally, between himself and the individual physicians.

During the discussions with management, Mr. Sullivan had no comment about the observation.

d) Does not have the above documents, readily available, for review and copying by designated employees of FDA, at a location that is reasonably accessible to FDA employees.

During the inspection, Mr. Sullivan stated that the firm's computer, used to store all of the business records, had experienced a "hard drive crash", in the winter of 1996. He explained that **consequently all records from 1994 to December 1996 have been lost.** I asked if the firm had any system for backing up data or programs. Mr. Sullivan stated that he did not have any back up system for those records. I specifically asked if he had any invoices for his clients, that mentioned the firm's "beam shaper" or software, which I stated a client had already supplied me with a copy. Mr. Sullivan replied that all of those records were lost in the hard drive crash. When I asked Mr. Sullivan if I could see the records from December 1996 to the present, he stated that he did not want to present any documents to me that would have a client's name, but that I could see his office to confirm that he did not have extensive records.

On 6/27/97, he showed me the office, located on the third floor of his residence. The office was extremely disorganized and was only (approximately) a 35' X 20' total area. The furniture in the room consisted of an L-shaped desk (with drawers), a small book shelf containing "off the shelf" software (████████████████████) and program manuals, a TV/stereo entertainment cabinet, other book shelves, a drum set. There was a copy of the IDE from ██████████ on the floor, and many loose papers on the desk. He stated that some of these loose papers were related to ExSull, Inc., but that he did not have the records I requested. There were no filing cabinets, and Mr. Sullivan stated that he did not keep records in any other location in the house. He also stated that he really didn't keep any hard copies of his business records.

During discussions with management, Mr. Sullivan had no comment about the observation.