

prior to installing them on the devices desktop computer, to see if they performed as intended. He also stated that the entire software program for the "beam shaper", including the calibration and safety modules, is only about [REDACTED] and can be contained on one floppy disk. He stated that he is responsible for all initial installations. He said that (in most cases) he installs updated programs, or sends them via E-Mail to the physician for them to install. Mr. Sullivan had not tested/verified any of these methods of installation (floppy disk or E-Mail).

On 6/25/97, Mr. Sullivan and I simultaneously (and unplanned) arrived at one of his clients. Mr. Sullivan and the physician informed me that Mr. Sullivan was there to calibrate the device. Mr. Sullivan gave his permission for me to observe the calibration procedure. I was allowed to examine the optical compartment, including the "beam shaper" or "beam sculptor", designed by Mr. Sullivan. Mr. Sullivan would not let me photograph this part of the device. I observed that the "beam shaper" has three motors that control the iris, the slit former and a motor for rotating the slit, once it is formed. It resides between the second of two lenses, and the angling mirror (see Attachment 5). In addition, I observed Mr. Sullivan utilizing a calibration program (residing on the device's/client's computer) that he confirmed he had developed. He also stated that this calibration software, is part of the same program he developed and installs in each of the devices he assembles for his client's. The program controls the "beam shaping" mechanism during the operation of the laser, and also contains the calibration modules. Mr. Sullivan would not allow me to have a printout of the screen, during this calibration process, nor would he provide me with any material regarding the program.

On 6/26/97, Mr. Sullivan confirmed that the "beam shaper" is really the "Controllable Iris/Slit with Laser Pulsar", by showing him a copy of an invoice from ExSull, Inc. to a local client (that lists the "Controllable Iris/Slit with Laser Pulsar") and having him state that this is that mechanism. I then asked if the software program is installed on all of the devices he has assembled for his client's. He replied that there might be some slight variations, due to the individual requirements of the client's, but that the control and alarm functions are the same.

2. The firm does not follow GMP regulations in that:

During the inspection, Mr. Sullivan repeatedly stated