

vision. She was informed that she should wait for the full recovery time, after which, further surgery could be attempted. Mr. Sullivan explained that the patient did not wait the full time, and went to the second physician, who used a [REDACTED] to remove a [REDACTED] disc of the cornea, for pathology screening. That patient finally had to have a corneal transplant.

OBJECTIONABLE CONDITIONS AND DISCUSSIONS WITH MANAGEMENT:

1. The firm does not have any software validation data for the software program specifically developed (by the firm) for controlling the "beam shaping" or "sculpting" mechanism (sometimes referred to as a "Controllable Iris/Slit with Laser Pulsar", and also designed by the firm), that the firm sold to and installed in approximately [REDACTED] Ophthalmological Excimer lasers located in Physician's offices, sometime between August 1994 and October 1996.

During the inspection, Mr. Sullivan informed both myself and Investigator Despina that he personally developed the software that controls the "beam shaper". Later in the inspection, Mr. Sullivan informed me that he designed the hardware for the "beam shaper" or "beam sculptor", as well as, the software that controls that hardware. He stated that his program was written in [REDACTED] and that three versions have been made, of that software. He informed me that he had no documentation or procedures for upgrading or changing the program (at the [REDACTED]). In addition, he could not provide any information regarding which of the software versions are in any of the particular devices, stating that he did not keep any of those records. He also explained that he has not upgraded any of the earlier versions of the software program, that might be on any of the "older" devices. Mr. Sullivan explained that he has no review or approval process for the changes to the software. He stated that he checks the changes by comparing the source codes, between the previous version and the "changed" version, to see if the source code was changed. I asked if he then tests the software, to verify that the changes performed as intended. He stated that he did not, and that the software would be tested at the physicians office, either by himself or an employee of the physician. He explained that the testing by the physicians concentrates on the excimer laser as a whole, and not on any of the individual software programs/components.

During the inspection, on 6/26/97, Mr. Sullivan stated that he did not test the software versions of his program