

component and a suggested component supplier, for each of them. According to Mr. Sullivan, this entire process (the exchange of laser beam requirements and the design specifications) is all done via telephone or personal visits, and he does not have any written records of the design specifications. He stated that each individual physician should have those records.

7. Determine whether Mr. Sullivan or his clients have submitted laser product reports or complied with the Radiation Health requirements for the devices he has built.

Mr. Sullivan informed me that he does not know if his client's have submitted laser product reports, but he thinks they have all complied with the Radiation Health requirements. He stated that this was the responsibility of the individual physician, to submit the reports and/or comply with the Radiation Health requirements. Any records regarding these issues would be kept at the individual physician's office.

8. Determine whether Mr. Sullivan is aware of any significant undercorrections or overcorrections or other injuries caused by the use of these laser devices. How is Mr. Sullivan handling complaints/problems with the devices.

During the inspection, on 4/9/97, Mr. Sullivan stated that he knew of no injuries with the device. He did say that in theory the laser would have some patients possibly experiencing overcorrection, but that the majority would experience a slight undercorrection, which might require additional treatment. In addition, he explained that there has been no hazing or scaring, with the devices. He stated that the physicians handle all of the complaints from the patients, and that he is not aware of any major complications. He did mention one patient who is suing one of his client's, but that the device did not cause the injury. He stated that a second physician, one that the patient went to for a second opinion (after the initial [REDACTED], did the alleged injury.

On 6/27/97, Mr. Sullivan elaborated that the case of the law suite occurred in April 1995, and involved a woman who was [REDACTED]. Mr. Sullivan stated that a correction of [REDACTED] requires a much longer recovery time. He explained that this is why most of the physicians will undertake this amount of correction in "stages". He stated that the patient returned to the physician who had performed the original [REDACTED] complaining of still blurry