-- under construction http://www.nutriwatch.org (nutrition facts and fallacies) http://www.ncahf.org (National Council Against Health Fraud) http://www.chsourcebook.com (consumer health sourcebook)

Editor, Consumer Health Digest http://www.ncahf.org/digest/chd.html
Publisher, Chiropractic News Digest
http://www.quackwatch.org/00AboutQuackwatch/chd.html
Donations of $1 to $50 to help support Quackwatch can be made through
http://s1.amazon.com/exec/varzea/pay/T1X6GUTTCLU3T4

Herb Nevyas

From: Stephen Barrett, M.D. [sbinfo@quackwatch.org]
Sent: Tuesday, July 29, 2003 9:54 PM
To: Herb Nevyas:
Subject: Yahoo Involvement

It looks like Yahoo is in the Web hosting business:
http://webhosting.yahoo.com/ps/wh/prod/

Here are Yahoo's "Terms of Service"
http://docs.yahoo.com/info/terms/

Included is this paragraph:
You agree to not use the Service to:
a. upload, post, email, transmit or otherwise make available any Content that is unlawful, harmful, threatening, abusive, harassing, tortious, defamatory, vulgar, obscene, libelous, invasive of another's privacy, hateful, or racially, ethnically or otherwise objectionable;

You should send a complaint by email to abuse@yahoo.com

Also send one to one of their top lawyers jsobel@yahoo-inc.com

The letters should state that the site is violating their terms of service.
The first round should simply provide the facts and should not threaten.
--

Stephen Barrett, M.D.
Board Chairman, Quackwatch, Inc.
NCAHF Vice President and Director of Internet Operations P.O. Box 1747, Allentown, PA 18105
Telephone: (610) 437-1795

http://www.quackwatch.org (health fraud and quackery) http://www.chirobase.org (guide to chiropractic) http://www.dentalwatch.org (guide to dental care) http://www.homeowatch.org (guide to homeopathy) http://www.ihealthpilot.org (under construction) http://www.mlmwatch.org (multi-level marketing) http://www.naturowatch.org (naturopathy) -- under construction http://www.nutriwatch.org (nutrition facts and fallacies) http://www.ncahf.org (National Council Against Health Fraud) http://www.chsourcebook.com (consumer health sourcebook)

Editor, Consumer Health Digest http://www.ncahf.org/digest/chd.html
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Donations of $1 to $50 to help support Quackwatch can be made through
http://s1.amazon.com/exec/varzea/pay/T1X6GUTTCLU3T4

Herb Nevyas

From: Stephen Barrett, M.D. [sbinfo@quackwatch.org]
Sent: Tuesday, July 29, 2003 9:52 PM
To: Herb Nevyas:
Subject: Fwd: lasik surgery

```
>Return-Path: <sbinfo@ComCAT.COM>
>X-Original-To: sbinfo@enter.net
>Delivered-To: sbinfo@enter.net
>Received: from localhost (localhost [127.0.0.1])
>      by mmail.enter.net (Postfix) with ESMTP id 28A63D5613
>      for <sbinfo@enter.net>; Mon, 28 Jul 2003 22:36:51 -0400 (EDT)
>Received: from mmail.enter.net ([127.0.0.1])
>  by localhost (rmail2.enter.net [127.0.0.1:10024]) (amavisd-new) with
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>(EDT)
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>      for <sbinfo@enter.net>; Mon, 28 Jul 2003 22:36:50 -0400 (EDT)
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>h6T2a2t0020154
>      for <sbinfo@enter.net>; Mon, 28 Jul 2003 22:36:02 -0400 (EDT)
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>      by smu0161.ComCAT.COM (8.12.9/Submit) id h6T2a1F9020116
>      for sbinfo@enter.net; Mon, 28 Jul 2003 22:36:01 -0400 (EDT)
>Received: from web10502.mail.yahoo.com (web10502.mail.yahoo.com
>[216.136.130.152])
>      by smu0161.ComCAT.COM (8.12.9/mh-s/20030519) with SMTP id
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>      for <victims@quackwatch.com>; Mon, 28 Jul 2003 22:35:48 -0400 (EDT)
>Message-ID: <20030729023547.90133.qmail@web10502.mail.yahoo.com>
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>Mon, 28 Jul 2003 19:35:47 PDT
>Date: Mon, 28 Jul 2003 19:35:47 -0700 (PDT)
>From: DOM MORGAN <djm0860@yahoo.com>
>Subject: lasik surgery
>To: victims@quackwatch.com
>
>is not all it's hyped up to be for patients who are not candidates.  i
>was told numerous times before having had lasik that i was a good
>candidate from a supposedly reputable laser center (nevyas eye
>associates - bala cynwyd, pa...whom you have articles
>written by).  my complete story is at:
>       www.lasiksucks4u.com
>these people ruined my eyes, my vision, and my life!!
>there are a growing number of people damaged by this procedure, who
>were told they were good candidates.
>when does it stop?
>
>dom
```

Herb Nevyas

From: Stephen Barrett, M.D. [sbinfo@quackwatch.org]
Sent: Tuesday, July 29, 2003 9:11 PM
To: Herb Nevyas:
Subject: Whois Information

"lasiksucks4u.com" is registered with whois.melbourneit.com:

Domain Name..... lasiksucks4u.com
Creation Date..... 2002-02-08
Registration Date.... 2002-02-08
Expiry Date..... 2004-02-08
Organisation Name.... Dominic J Morgan
Organisation Address. PO BOX 168
Organisation Address.
Organisation Address. Marlton
Organisation Address. 08053
Organisation Address. NJ
Organisation Address. UNITED STATES

Admin Name..... Dominic J Morgan
Admin Address..... PO BOX 168
Admin Address.....
Admin Address..... Marlton
Admin Address..... 08053
Admin Address..... NJ
Admin Address..... UNITED STATES
Admin Email..... lasiksucks4u@lasiksucks4u.com Admin Phone..... 856-979-5123
Admin Fax.....

Tech Name..... YahooDomains Techcontact Tech Address..... 701 First Ave.
Tech Address.....
Tech Address..... Sunnyvale
Tech Address..... 94089
Tech Address..... CA
Tech Address..... UNITED STATES
Tech Email..... domain.tech@YAHOO-INC.COM Tech Phone..... +1.6198813096 Tech
Fax.....
Name Server..... ns8.san.yahoo.com
Name Server..... ns9.san.yahoo.com

Whois Server Version 1.3

Domain names in the .com and .net domains can now be registered with many different competing registrars. Go to http://www.internic.net for detailed information.

Domain Name: LASIKSUCKS4U.COM
Registrar: MELBOURNE IT, LTD. D/B/A INTERNET NAMES WORLDWIDE Whois Server: whois.melbourneit.com Referral URL: http://www.melbourneit.com Name Server: NS8.SAN.YAHOO.COM Name Server: NS9.SAN.YAHOO.COM
Status: ACTIVE
Updated Date: 27-jan-2003
Creation Date: 08-feb-2002
Expiration Date: 08-feb-2004

>>> Last update of whois database: Tue, 29 Jul 2003 18:02:09 EDT

Quackwatch Home Page

Pneumatic Trabeculoplasty (PNT) for Glaucoma

Stephen Barrett, M.D.

Glaucoma is a group of disorders in which increased pressure within the eyeball (intraocular pressure) can damage the eye and cause impaired vision, ranging from slight impairment to complete blindness. The pressure is caused by an imbalance between production and drainage of the intraocular fluid (aqueous humor). Most cases of glaucoma can be controlled with eyedrops [1]. Oral medication and/or surgery may be used when control cannot be achieved with the drops.

In 1997, the Arizona Glaucoma Institute (AGI), of Scottsdale, Arizona, began offering a "new treatment" for open-angle and pigmentary glaucoma using a patented vacuum-ring device. Devices of this type are FDA-approved for stabilizing the eye during refractive (lens) surgery, but they are not approved for use in treating glaucoma. The institute's parent company, Coronado Industries , marketed the device through another subsidiary called Ophthalmic International. Patent information for the device states:

The open angle glaucoma treatment apparatus is a vacuum source and a vacuum applicator coupled by a hose. The vacuum applicator is an eye ring or an eye cup that is placed on the frontal surface of an eye. Suction (negative pressure) in the range of 10 to 30 mm. Hg. is applied by the vacuum source, which will fixure the ring or cup to the eye, or alternatively pressure is applied for 15 to 120 seconds. A second treatment is recommended later. It could be within twelve hours, on the following day, or within the next couple of days [2].

An AGI brochure stated that a 2-minute treatment with the device "lowers intra-ocular pressure in most cases." [3] Another institute document states that during the previous four years, "a good number" of patients have been taken off of their medication completely and that "a number of patients" have remained on medication but required reduced dosage [4]. PNT costs about $200 per treatment. In September 1997, the institute offered free glaucoma screenings in connection with its"grand opening." [5]

In early 1998, an Arizona investment firm seeking investors for Coronado Industries issued a private offering summary which noted that the AGI's medical director, ophthalmologist Leo D. Bores, M.D., had originated the radial keratotomy procedure [6]. The solicitation, intended "for broker-dealer internal use only," projects after-tax earnings of $12 million in 1998, $46 million in 1999, and $99 million in the year 2000. The solicitation also states that the proceeds will be used to open additional Glaucoma Treatment Centers and that Coronado Industries believes that "insurance companies will . . . quickly approve payment for the new device and procedure since it is projected to reduce the cost of long-term care costs associated with alternative treatments." [6] However, the company's Form SB-2 Registration Statement filed with the Securities and Exchange Commission on 8/24/98, noted receipts of $179,767 and an overall loss of $648,702 for the first half of 1998 [7]. The report also stated:

In March 1998, the company's Scottsdale treatment center began receiving Medicare payments for . . . the PNT procedure. There is no assurance that these payments will continue . . . and as to when, if ever, the Company will receive payments at . . . additional centers from third-party payors [7].

Safety and Effectiveness Questioned

The fluid within the eyeball normally drains through the trabecular meshwork, a thin net-like band that lies between between the cornea (the clear window of the eye) and the sclera (the white portion of the eye). Glaucoma usually occurs because the mesh becomes clogged or is unable to allow sufficent drainage. When this happens, since fluid production continues, intraocular pressure builds up.

Normal eye pressures range from 8 to 20 millimeters of mercury (mm Hg). In high-pressure glaucoma, the levels range from 21 to 40. In rare cases, new patients present with higher levels. The higher the pressure, the more likely that optic nerve damage will occur. PNT is postulated to reduce pressure within the eye by squeezing fluid out through the trabecular meshwork. However, fluid production continues, so unless the procedure can improve the drainage system itself, any pressure reduction would be short-lived.

PNT temporarily squeezes the front of the eyeball and raises the intraocular pressure to 65 and perhaps even higher. In someone with an already damaged optic nerve, this could be serious. The accepted treatment for glaucoma is to lower the pressure with medication or surgery. Experiments in monkeys have demonstrated that sudden pressure elevations can compromise the blood supply to the optic nerve and accelerate nerve cell death in already weakened cells [8,9], and human experiments have found that acute pressure increases can increase cupping of the optic nerve [10,11]. Two cases have been reported of patients who lost part of their vision following LASIK operations during which their intraocular pressure was temporarily raised when a suction ring was applied to their eyeball [12,13]. For these reasons, until proven safe, PNT should be viewed with caution. Damage from high intraocular pressure may not be immediately apparent. As a result, patients having PNT may not be able to tell whether they are being harmed until it is too late to reverse the damage. Proof of safety and effectiveness would require long-term studies showing not only that intraocular pressure is lowered, but also that the patients' visual fields have not been adversely affected.

To date, no peer-reviewed journal has published a study demonstrating that PNT actually works or is safe. Preliminary reports by Dr. Bores, a Mexican ophthalmologist (Guillermo Avalos, M.D.), and ophthalmologist John LiVecchi, M.D. (described in the brochure as a director and major shareholder of Coronado Industries) have claimed positive results. A report on Coronado Industries' Web site in November 1998 stated that at least 250 patients had been treated for up to 3.5 years, with "maintenance therapy as frequently as every 2-3 months to yearly." These reports claimed various levels of effectiveness, with the drop in pressure being greatest in people whose problem was least severe when they sought treatment. However, a study conducted at the Duke University School of Medicine found that PNT did not lower intraocular pressure among 20 patients with uncontrolled glaucoma. Each patient had one eye treated while the other served as a control. Measurements at one hour, two hours, one day, one week, one month, and three months later found no reduction of intraocular pressure or improvement in the drainage of fluid from within the eye [14]. The reports from Drs. Bores, Avelos, and LaVecchi did not contain such comparative data or compare their patients to a control group of similar patients who did not undergo PNT.

FDA Objections

Documents obtained with a Freedom of Information Act request indicate that in February 1998, the FDA issued a warning letter to Ophthalmic International president G. Richard Smith. The letter stated:

During an inspection of your firm conducted between November 25 and December 11, 1997,

our investigators determined that your firm distributed two vacuum fixation devices with suction rings to the Arizona Glaucoma Institute. . . for use in treating patients with glaucoma using a pneumatic trabeculoplasty (PNT) procedure. These products are devices as defined by . . . the Federal Food, Drug, and Cosmetic Act.
Your vacuum fixation devices are adulterated . . . in that they are Class III devices. . . and do not have approved applications for investigational device exemption (IDE). . . . Your . . . devices are also misbranded . . . in that a notice or other information respecting the devices was not provided to the FDA as required [15].
The letter indicated that because the device is not approved for the treatment of glaucoma, the FDA regards it as a new device for which FDA approval is required and that:
The sponsors of investigations, investigators, or any persons acting for or on behalf of a sponsor or an investigator may not promote or test market an investigational device or represent that it is safe or effective for the purpose for which it is being investigated.
Smith replied that the vacuum fixation device does have an IDE and should not be considered a Class III device, that an Institutional Review Board (IRB) had determined that the device did not pose an unreasonable risk to patients, and that his company plans to submit an application to broaden the way the device is used [16]. However, an FDA official responded that the device had not been formally classified, that new devices are automatically placed in Class III, and that the agency disagreed with the IRB's conclusion [17]. In August 1998, the company submitted an IDE application [7], which the FDA rejected.

Disciplinary Action

In March 1999, Dr. Bores announced that he had retired from clinical practice but would continue to direct research at the American Eye Institute , with which AGI had merged [18]. In December 1999, after additional communication with the FDA, Ophthalmic International was given permission to conduct a small "feasibility study." [19] Federal regulations state that during clinical studies, no investigator or sponsor can commercially distribute an unapproved device, charge subjects more than the amount needed to cover costs, or represent that the device is safe or effective for its intended purpose. According to information from the Arizona Medical Board, Bores did all of these things, lacked FDA approval to conduct any PNT studies, and improperly collected Medicare payments for patients treated between December 1997 and February 1999. In April 2003, the board reprimanded Bores and placed him on two years' probation under which he is barred from conducting studies that do not meet FDA criteria and must reimburse Medicare for $15,539.81 that he had been paid for the 1997-1999 treatments [19].

The Bottom Line

Pneumatic trabeculoplasty has not been proven safe or effective for treating glaucoma; and Coronado Industries' vacuum fixation device lacks FDA approval for such use. It remains to be seen whether additional research will demonstrate benefit.

For Additional Information

Additional information about glaucoma can be obtained from:

- American Academy of Ophthalmology
- Glaucoma Foundation : (800) 452-8266. Has a 20-page brochure online.
- Glaucoma Research Foundation : (800) 826-6693.
- National Eye Institute
- State ophthalmic or optometric boards

- Don't Waste Money on Overpriced Eyedrops

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4. "Dear Glaucoma Patient." Letter from Arizona Glaucoma Institute. Undated, acquired in 1997.
5. Coronado Industries, Inc., announces grand opening of exclusive glaucoma treatment center . Press release, Sept 5, 1997.
6. Private offering summary. $5,600,000. Coronado Industries, Inc. (NASDAQ Symbol CDIK) 12% 5-year Convertible Notes. Fox & Company Investments , Phoenix, Arizona, January 29, 1998.
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8. Shirakashi M. The effects of intraocular pressure elevation on optic nerve axonal transport in the monkey . Acta Ophthalmologica 68:37-43, 1990.
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16. Smith GR. Letter to FDA Compliance Officer Dannie E. Rowland, March 30, 1998.
17. Messa EC. Letter to G. Richard Smith, May 4, 1998.
18. Bores LD. A notice from the Arizona Glaucoma Institute, February 26, 1999.
19. Consent agreement and order for letter of reprimand and probation. In the matter of Leo Bores, M.D. Arizona Medical Board Case # MD-97-0948, April 4, 2003.

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This article was updatd on May 31, 2003.

Title 21—Food and Drugs

Chapter 1

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 56 — Institutional Review Boards

Subpart A — General Provisions

§56.101 Scope.

(a) This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration under sections 505(i), 507(d), and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§56.102 Definitions.

As used in this part:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-392)).

(b) "Application for research or marketing permit" includes:

(1) A color additive petition, described in Part 71.

(2) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for a use which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §170.35.

(3) A food additive petition, described in Part 171.

(4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in §180.1.

(5) Data and information regarding a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) An investigational new drug application, described in Part 312 of this chapter.

(7) A new drug application, described in Part 314.

(8) Data and information regarding the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in Part 320.

(9) Data and information regarding an over-the-counter drug for human use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in Part 330.

(10) Data and information regarding an antibiotic drug submitted as part of the procedures for issuing, amending, or repealing regulations for such drugs, described in §314.300 of this chapter.

(11) An application for a biological product license, described in Part 601.

(12) Data and information regarding a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, as described in Part 601.

(13) An "Application for an Investigational Device Exemption," described in Parts 812 and 813.

(14) Data and information regarding a medical device for human use submitted as part of the procedures for classifying such devices, described in Part 860.

(15) Data and information regarding a medical device for human use submitted as part of the procedures for establishing, amending, or repealing a standard for such device, described in Part 861.

(16) An application for premarket approval of a medical device for human use, described in section 515 of the act.

(17) A product development protocol for a medical device for human use, described in section 515 of the act.

(18) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such products, described in section 358 of the Public Health Service Act.

(19) Data and information regarding an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, as described in §1010.4.

(20) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in §1010.5.

(21) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in Subpart D of Part 1003.

(c) "Clinical investigation" means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results

(W-S) 407: W-S is a 32 year old male who underwent unilateral LASIK surgery on the left eye with the Nevyas Excimer Laser on 4/9/1998. The surgery was unremarkable except that pannus was noted as an ablation complication. Target postoperative manifest refraction was –1.50 MRSE. At 6 months postoperatively, the eye had a manifest refraction of 0.50 x –0.25 x 90, with an UCVA of 20/40 and BSCVA of 20/30. At 12 months postoperatively, the refraction improved to 0.00 x –0.75 x 165 with the UCVA and BSCVA both reported as 20/30.

(C-H) 612: C-H is a 41 year old female who underwent LASIK surgery on the left eye with the Nevyas Excimer Laser on 9/10/1998. Preoperatively, the eye had a manifest refraction of –8.00 x-1.50 x164 with an UCVA of 20/1000 and BSCVA of 20/20. The eye was intentionally undercorrected with a target postoperative refraction of –1.25 D MRSE. At 6 months postoperatively, the manifest refraction was –1.00 x-0.50 x 90 with an UCVA of 20/70 and BSCVA of 20/40. BSCVA measured at an unscheduled visit performed one month later, and at all subsequent scheduled visits, was 20/20. The transient decrease in BSCVA observed at 6 months was most likely due to technician error.

(L-W) 825/826: L-W is a 40 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 9/2/1999. Preoperatively, the manifest refraction was –8.75 x –0.50 x 100 in the right eye and –8.75 x-0.75 x 38 in the left eye, with both eyes having an UCVA of 20/1000 and BSCVA of 20/20. A monovision treatment was performed with the left eye intentionally undercorrected to a target postoperative refraction of –1.25 D MRSE and the right eye targeted to plano. At 6 months postoperatively, the right eye was overcorrected with a manifest refraction of 1.75 x –1.25 x 135, with an UCVA of 20/50 and a BSCVA of 20/30. The left eye had attained its targeted undercorrection with a manifest refraction of –1.00 x –0.50 x 15, with a distance UCVA of 20/70 and BSCVA of 20/40. No additional visit information is available for either of these eyes.

(M-N) 928: M-N is a 50 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 5/7/1999. The intraoperative and postoperative course of the right eye was unremarkable with no change in BSCVA. A superotemporal tear on the corneal flap edge was noted as a keratectomy complication during the surgery on the left eye. Preoperatively, the eye had a manifest refraction of –4.00 x –1.00 x 175, with a UCVA of 20/200, and a BSCVA of 20/20. The eye was intentionally undercorrected for monovision with a target refraction of –1.50D MRSE. At 12 months postoperatively, the left eye had a 2-line loss in BSCVA (BSCVA = 20/30). At the 24 month end of study visit, the left eye had a manifest refraction of –1.00 x-0.50 x 110 with an UCVA of 20/30 and BSCVA of 20/20.

(P-D) 1019: P-D is a 55 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 8/12/1999. The

intraoperative and postoperative course of the right eye was unremarkable, with no change in BSCVA (BSCVA = 20/20) at all visits. The left eye reported a single 2-line loss in BSCVA at the 12-month visit. Manifest refraction was +0.50x –1.50 x 107 with an UCVA of 20/30. BSCVA was reported as 20/20 at all other visits. The isolated report of BSCVA loss is believed due to technician error or variability in obtaining the BSCVA measurement.

(R-A) 1021/1022: R-A is a 47 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 8/12/1999. Preoperatively, the manifest refraction was –6.00 x-2.00 x 165 in the right eye and –5.25 x –2.50 x 168 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/15. A monovision treatment was performed with a targeted postoperative refraction of +0.25 D MRSE in the right eye and –1.25 D MRSE in the left eye. Both eyes reported a BSCVA of 20/25 (2 line loss) at 18 months postoperatively. Manifest refraction at this visit was +1.25 x –0.75 x 158 with a UCVA of 20/25 in the right eye and –0.50 x –0.50 x 65 with a UCVA of 20/25 in the left eye. At the 24-month end of study visit, the left eye had a manifest refraction of –0.75 x –0.25 x 150, UCVA of 20/30, and BSCVA of 20/20. The right eye had a LTK procedure performed at ~18 months postoperatively, and at 12 months post-LTK the manifest refraction is 0.00 x-0.75 x 20 with an UCVA of 20/25 and a BSCVA of 20/20.

(J-R) 1037: J-R is a 23 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 12/20/1999. The intraoperative and postoperative course of the left eye was unremarkable, except for the complaint of redness and dryness and 6 months postoperatively. Preoperatively, the right eye had a manifest refraction of 06.50 x –0.50 x 103, with a UCVA of 20/1000 , and a BSCVA of 20/20 . The eye was intentionally overcorrected with a target refraction of +0.25D MRSE. The right eye had a single report of BSCVA loss at the 24-month end of study visit. The manifest refraction in the right eye of –0.50 x –0.75 x 90 was unchanged from the 12-month visit. UCVA at 24 months was 20/30, compared to 20/25 at 12-months, and BSCVA was 20/30. BSCVA was reported to be 20/20 at all other postoperative visits, including the 12-month visit. The change in BSCVA is believed to be due to technician variability rather than any true change in vision, especially since the manifest refraction has remained stable throughout the postoperative course.

(D-P) 1107/1108: D-P is a 54 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 9/17/1999. Preoperatively, the manifest refraction was –6.50 x-0.00 x 0 in the right eye and –6.50 x –0.00 x 0 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. A monovision treatment was performed with a targeted postoperative refraction of –2.00 D MRSE in the right eye and plano in the left eye. The postoperative course of each eye was unremarkable, except for the notation of two inferior spots of stain on slit lamp examination of the right eye at 1 month postoperatively. Both eyes reported a BSCVA of 20/30 (2 line loss) at 6 and 12 months postoperatively. At 12 months postoperatively, the manifest refraction is –0.75 x 0x 0 for the intentionally

undercorrected right eye (distance UCVA = 20/40) and +0.75 x 0 x 0 (distance UCVA = 20/25). The patient is happy with the current vision and offers no complaints.

(C-W) **1191/1192**: C-W is a 54 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 12/16/1999. Preoperatively, the manifest refraction was –6.75 x-2.50 x 25 in the right eye and –5.50 x –2.25 x 163 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. The targeted postoperative refraction was plano for both eyes. The postoperative course was unremarkable except for the complaint of halos and glare in both eyes at 1 to 3 months post-LASIK. BSCVA in the left eye ranged between 20/100 at 6months and 20/40 at 12 months postoperatively, primarily due to a high degree of residual cylinder (range –2.25 to –3.75 D). The right eye had a single report of a 2-line loss in BSCVA at 9 months postoperatively (BSCVA=20/30) with a moderate amount of residual cylinder (range = -1.75 to –2.75 D) reported postoperatively. At 12 months post-LASIK, the manifest refraction was +1.75 x –2.25 x 45 in the right eye (UCVA = 20/30; BSCVA =20/40) and +0.75 x –1.75 x 135 (UCVA = 20/30; BSCVA = 20/20). An AK procedure was performed on each eye to reduce the amount of residual cylinder, followed by a LASIK retreatment procedure in the left eye to improve the refractive error. At 1 month after the AK procedure, the right eye has a manifest refraction of –1.00x –0.75 x 22 (UCVA = 20/70; BSCVA = 20/40). Further improvement in vision is expected as the eye continues to heal from the procedure. The left eye, at 3 months after the last refractive procedure, has a manifest refraction of +0.50 x 0 x 0 (UCVA = 20/25; BSCVA = 20/25.).

(T-J) **1204**: T-J is a 39 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 1/13/2000. The surgical procedure was unremarkable except for the occurrence of a tear superiorly on corneal flap of the right eye, which was noted as a keratectomy complication. Preoperatively, the manifest refraction was –7.50 x –2.25 x 164 in the left eye and –8.25 x –2.00 x 13 in the right eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. At 3 months postoperatively, the subject complained of starbursts around headlights, ghost images, and problems with distance vision in both eyes. At 6 months postoperatively, interface haze was observed in both eyes and epithelial haze was noted in the left eye only, with each eye reporting a 1-line loss in BSCVA (BSCVA = 20/25). At 18 months postoperatively, a mild superior decentration was observed in the right eye and the patient complained of double vision in this eye. Manifest refraction in the right eye was –0.75 x –1.25 x 49, with an UCVA of 20/50 and BSCVA of 20/30 (2-line loss in BSCVA). At the 24 month end of study visit, the BSCVA returned to 20/25 in the right eye and BSCVA was reported as 20/20 in the left eye.

(R-S) **1235**: R-S is a 22 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 2/17/2000. Preoperatively, the manifest refraction was –3.75 x –2.00 x 25 in the right eye and –4.00 x –2.25 x 160 in the left eye. Target postoperative refraction for both eyes was +0.25 D MRSE. The intraoperative and postoperative course was unremarkable for both eyes. Both eyes were

evaluated at 3 months (BSCVA = 20/20 in both eyes) and then lost to follow-up until the 24 month end of study visit. At 24 months postop, the right eye had a manifest refraction of –1.00 x 0.00 x 0, UCVA of 20/25, and BSCVA of 20/15. The left eye reported a manifest refraction of –0.75 x –1.50 x 120, UCVA of 20/40, and BSCVA of 20/30 (2-line loss of BSCVA). Since this patient missed all visits between the 3 and 24months postoperatively, it is unknown if the loss in BSCVA was progressive or an isolated occurrence.

(L-A) 1236: L-A is a 50 year old female who underwent unilateral LASIK surgery on the left eye with the Nevyas Excimer Laser on 8/26/1999. Preoperatively, the eye had a manifest refraction of –1.25 x –2.50 x 178, with a UCVA of 20/200 and BSCVA of 20/15. Target postoperative refraction was +0.25D MRSE. The intraoperative and postoperative course was unremarkable for this eye, except for the complaint of fluctuating vision at the 6 and 9 month visits. At 6 months postoperatively, the eye had a manifest refraction of 0.00 x 1.75 x 170, UCVA of 20/100, and BSCVA of 20/60 (5-line loss in BSCVA). At 9 months postoperatively, the manifest refraction was 0.50 x –2.50 x 175, UCVA of 20/40, and BSCVA of 20/20. The BSCVA was recorded as 20/20 at the 1 and 3 month visits and for all visits after 9 months. The transient loss in BSCVA at 6 months is related to the fluctuating vision experienced by the patient at the 6 and 9 month visits. The cause for the fluctuating vision is unknown.

(Y-V) 1284: Y-V is a 37 year old male who underwent LASIK surgery on the right with the Nevyas Excimer Laser on 3/16/2000. Preoperatively, the right eye had a manifest refraction of –3.25 x –0.75 x 20, UCVA of 20/400 and BSCVA of 20/15. The target postoperative refraction was plano. The patient was noncompliant with the postoperative visit schedule, missing all visits between 1 week and 12 months post-LASIK and the 18 and 24 month visits. At 12 months postoperatively, the right eye had a manifest refraction of –1.50 x –0.75 x 15, UCVA of 20/80, and a BSCVA of 20/25 (2-line loss in BSCVA).

(J-E) 1288: J-E is a 55 year old female who underwent unremarkable bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 3/16/2000. The postoperative course of the right eye was unremarkable, with no change in BSCVA. Preoperatively, the right eye had a manifest refraction of –6.00 x 0.00 0 and the left eye had a manifest refraction of –8.75 x –0.00 x 0. Both eyes had a preoperative UCVA of 20/1000 and a BSCVA of 20/20 . The left eye was intentionally undercorrected with a target refraction of –1.75D MRSE. At 6 months postoperatively, the manifest refraction in the left eye was –3.50 x 0 x 0. The UCVA was reported to be 20/25 and the BSCVA to be 20/400. Since the UCVA was ranged between 20/50 and 20/400 and the BSCVA ranged between 20/20 and 20/25 at all prior and all subsequent visits, this isolated loss in BSCVA appears to be a data entry error on the source documents and that the UCVA and BSCVA readings were reversed when the measurements were recorded.

(S-C) **1457**: S-C is a 42 year old female who underwent unremarkable bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 7/7/2000. Postoperative course of the left eye was unremarkable, with no loss in BSCVA at the last recorded visit. Preoperatively, the right eye had a manifest refraction of –8.50 x 1.25 x 8 and the left eye had a manifest refraction of –8.25 x –1.00 x 165. Both eyes had a preoperative UCVA of 20/1000 and a BSCVA of 20/20. The left eye was intentionally undercorrected with a target refraction of –1.75D MRSE and target refraction in the right eye was +0.25D MRSE. At 6 months postoperatively, the right eye had a manifest refraction of –2.25 x –0.25 x 157, UCVA of 20/200, and a BSCVA of 20/40 (3-line loss in BSCVA). No other information is available on the outcome of this eye.

(J-Y) **1499/1500**: J-Y is a 38 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 7/13/2000. Preoperatively, the manifest refraction was –10.00 x-0.75 x 105 in the right eye and –7.25 x –0.50 x 60 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. A monovision treatment was performed with a targeted postoperative refraction of –1.25 D MRSE in the right eye and +0.25 D MRSE in the left eye. At 12 months postoperatively, the right eye had a manifest refraction of –4.00 x –0.50 x 145, UCVA of 20/60, and BSCVA of 20/30 (2-line loss in BSCVA). A LASIK retreatment procedure was performed and at 6 months post-retreatment, the right eye had a manifest refraction of –1.00 x –0.25 x 80, UCVA of 20/50 and BSCVA of 20/25. The left eye had a single report of a 2-line loss in BSCVA (BSCVA – 20/30) at 12 month postoperatively; BSCVA was 20/20 at the 1 and 3-month visits and the patient missed the 6-month visit. At the 18-month postoperative visit, the manifest refraction in the left eye was –1.50 x –0.25 x 105, UCVA of 20/30, and BSCVA of 20/20. No further treatment is planned for either eye at this time and the patient continues to be followed actively in the study.

(A-B) **1529**: A-B is a 48 year old male who underwent unremarkable bilateral same-day LASIK surgery on the right and left eye with the Nevyas Excimer Laser on 8/11/2000. Preoperatively, the right eye had a manifest refraction of –7.25 x -1.00 x 110 and the right eye had a manifest refraction of –8.25 x –1.00 x 90. Preoperative UCVA was 20/1000 in both eyes and the BSCVA was 20/25 in the right eye and 20/20 in the left eye. A monovision treatment was performed with the left eye being intentionally undercorrected to a target of –1.25 D MRSE. The postoperative course was unremarkable in both eyes, except for the complaint at 3 months of the distance vision being blurry in both eyes. At 6 months postoperatively, the left eye reported a 2-line loss in BSCVA with a manifest refraction of –2.25 x –0.50 x 90, UCVA of 20/70, and BSCVA of 20/30. A LASIK retreatment procedure was performed on the left eye to reverse the monovision treatment; target post-retreatment refraction was +0.25 D. At 12 months post-retreatment, the left eye has a manifest refraction of 0.75 x –0.25 x 110, UCVA of 20/25, and BSCVA of 20/20.

(H-O) **1544**: H-O is a 45 year old female who underwent unremarkable bilateral same-day LASIK surgery on the right eye with the Nevyas Excimer Laser on 8/25/2000. Preoperatively, the right eye had a manifest refraction of –6.50 x –0.50 x 45 and the left

eye had a manifest refraction of –7.25 x –0.50 x 75. Preoperative UCVA was 20/1000 and BSCVA was 20/25 in both eyes. A monovision treatment was performed and the right eye was intentionally undercorrected with a target refraction of –1.50D MRSE. Postoperative course was unremarkable for both eyes, except the patient complained of problems with distance vision in both eyes at 6 months postoperatively. At this visit, the right eye had a manifest refraction of –1.00 x –0.25 x 45, UCVA of 20/50, and BSCVA of 20/40 (2-line loss in BSCVA); the left eye had a manifest refraction of –0.25 x –0.50 x 10, with a UCVA of 20/40 and BSCVA of 20/30 (1-line loss in BSCVA). Both eyes underwent LASIK retreatments to reverse the monovision. At 12 month postoperatively, both eyes have regained their preoperative BSCVA of 20/25.

(E-F) **1599/1600**: E-F is a 32 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 10/27/2000. Preoperatively, the manifest refraction was –12.00 x-0.00 x 0 in the right eye and –10.75 x –0.75 x 45 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. The targeted postoperative refraction was +0.25 D MRSE for both eyes. The intraoperative and postoperative courses were unremarkable for both eyes. The right eye reported a BSCVA of 20/30 (2 line loss) at 6 months postoperatively, which improved to 20/25 at 18 months post-LASIK. The left eye reported a single occurrence of a 2-line loss in BSCVA at the 18 month visit (BSCVA = 20/30). Manifest refraction at 18 months post-LASIK is –1.50 x 0.00 x 0 in the right eye and –0.50 x –0.75 x 165 in the left eye. Both eyes remain in follow-up and no treatment is planned at this time.

(P-A) **1714**: P-A is a 54 year old female who underwent bilateral LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 1/26/2001. Preoperatively, the manifest refraction was 7.75 x-2.00 x 180 in the right eye and –800 x –1.25 x 2 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. A monovision treatment was performed with a targeted postoperative refraction of +0.25 D MRSE in the right eye and –2.00 D MRSE in the left eye. The postoperative course for the left eye was unremarkable. At 6 months postoperatively, the right eye had a manifest refraction or +0.50 x –0.75 x 150, with an UCVA and BSCVA both reported to be 20/30 (2 line loss in BSCVA). At the last scheduled visit (12 months postop), the manifest refraction was +0.50 x –0.75 x150 in the right eye and –1.75 x-0.75 x 10 in the intentionally undercorrected left eye. Both eyes had a distance UCVA of 20/70 and distance BSCVA of 20/30 (2 line loss in BSCVA) in the right eye and 20/20 in the left eye.

(J-K) **1760/1761**: J-K is a 33 year old male who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 2/16/2001. Fine vertical movements during fixation were noted intraoperatively with the right eye. Preoperatively, the manifest refraction was –8.50 x-2.75 x 3 in the right eye and –9.00 x –3.00 x 165 in the left eye. Both eyes had a preoperative UCVA of 20/1000 and BSCVA of 20/20. A monovision treatment was performed with a targeted postoperative refraction of –0.75 D MRSE in the right eye and +0.25 D MRSE in the left eye.

Postoperatively, corneal wrinkles were noted in the flap of both the right and left eyes at 1 month and 3 months postoperatively. At 6 months postoperatively, an epithelial defect was noted in the left eye. The manifest refraction was –1.25 x-1.50 x 70 in the left eye with an UCVA of 20/100 and BSCVA of 20/50 (4 line loss in BSCVA). The patient was seen approximately every 6 weeks for the next 6 months, and BSCVA subsequently improved in the left eye to 20/30 at the next (7 month) visit and then fluctuated between 20/25 and 20/20 at each of the subsequent visits. The right eye had a measured BSCVA of 20/30 (2 line loss) at the 6 month visit with a BSCVA of 20/25 or 20/20 reported at each visit thereafter. At 12 months postoperatively, the right eye had a manifest refraction of –0.75 x –2.00 x 160, UCVA of 20/50, and BSCVA of 20/25. The left eye had a manifest refraction of –1.50 x –2.50 x 125, UCVA of 20/70 and BSCVA of 20/25. A retreatment was performed in each eye with a commercially available laser to improve vision. At 1 month postoperatively, the right eye has a manifest refraction of 0.00 x –0.25 x 28, UCVA and BSCVA of 20/25; the left eye has a manifest refraction of –0.50 x –0.75 x 60, UCVA of 20/40 and BSCVA of 20/25.

(J-H) 1949: J-H is a 53 year old female who underwent bilateral same-day LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 5/18/2001. The right eye was retreated at 3 months postoperatively to improve the refractive outcome and had a 1 line gain in BSCVA at 1 month post-retreatment. Preoperatively, the left eye had a manifest refraction of –5.00 x –1.75 x 180, with a UCVA of 20/1000 , and a BSCVA of 20/20 . The left eye was intentionally undercorrected for monovision with a target refraction of –1.75D MRSE. The postoperative course of the left eye was unremarkable except for the notation of a 2-line loss in distance BSCVA reported at the 6-month visit. At 6 months postoperatively, the manifest refraction was –2.50 x 0.00 x 0, with distance UCVA of 20/400 and distance BSCVA of 20/30, which is consistent with the monovision treatment performed in this eye.

(C-R) 2007: C-R is a 53 year old female who underwent unremarkable bilateral LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 5/31/2001. Preoperatively, the right eye had a manifest refraction of –7.00 x –0.75 x 29 and the left eye had a manifest refraction of –8.75 x –1.00 x153. Preoperative UCVA was 20/1000 and BSCVA was 20/20 in both eyes. A monovision treatment was performed with the right eye targeted for plano and the left eye intentionally undercorrected to a target of –2.00 D. Postoperative course in the left eye was unremarkable except for the notation of punctate staining at 1 month post-LASIK. The right eye was noted to have punctate staining at 1 month and SPK at 6 months post-LASIK. The right eye also had a 2-line loss in BSCVA at 6 months postoperatively, with a manifest refraction of –1.50 x –0.75 x 58, UCVA of 20/70, and BSCVA of 20/30. BSCVA was unchanged in the left eye, and the eye had a manifest refraction of –3.25 x –0.25 x 165, UCVA of 20/100, and BSCVA of 20/20. Both eyes were retreated at 6 months post-LASIK using a commercially available laser to reverse the monovision treatment. At 3 months post-retreatment, the manifest refraction is +0.50 x –0.50 x 115 in the right eye and +1.00 x –0.75 x 90 in the left eye. Both eyes have an UCVA of 20/20 and BSCVA of 20/20.

(D-M) 2182/2183: D-M is a 38 year old male who underwent unremarkable bilateral LASIK surgery on the right and left eyes with the Nevyas Excimer Laser on 4/30/1998. Preoperatively, the right eye had a manifest refraction of –4.25 x –2.00 x 170 and the left eye had a manifest refraction of –4.25 x –2.00 x 11. Preoperative UCVA was 20/400 and BSCVA was 20/40 in both eyes. A monovision treatment was performed with the right eye targeted for –0.625 D and the left eye intentionally undercorrected to a target of –2.25 D. It should be noted that this patient is a difficult patient to refract. The patient is uncooperative in performing the refractive procedures and refuses to try to read smaller lines on the distance visual acuity chart. Losses in BSCVA ranged between 2 and 6 lines in the right eye and between 1 and 6 lines that are inconsistent with the small residual refractive errors measured at each visit. A hard contact lens was tried in the right eye at 1 month postoperatively in an attempt to improve the BSCVA. BSCVA was 20/60 at this 1-month visit and remained unchanged at 20/60 with the hard contact lens at 2 months postoperatively. At the 24-month end of study visit, the patient has a manifest refraction of –0.50 x –0.50 x 60 in the right eye and –1.00 x –0.25 x 45 in the left eye, with an UCVA of 20/100 and BSCVA of 20/80 (4-line loss in BSCVA) in each eye. We believe the loss in BSCVA experienced by this patient is directly linked to his unwillingness to perform the visual acuity testing as instructed and is not a true reflection of his visual outcome.

Subj: **Confirm this please**
Date: 8/7/02 3:08:20 PM Eastern Daylight Time
From: BSFant
To: Newyas

Rich,
Can you confirm the UCVA/BSCVA preop values for the following patients. Current values in the database are listed.

Joseph Mack right eye	UCVA = 20/20	BSCVA = 20/400	→ UCVA 20/1000 → BCVA 20/20
Germaine Diehl right eye	UCVA = 20/20	BSCVA = 20/200	OS WTS screened up UCVA 20/400 screened up switched 20/20
William Smith left eye	UCVA = 20/100	BSCVA = 20/100	OS PHH OS BCVA 20/20
Soo Eng right eye	UCVA = 20/40	BSCVA = 20/50	→ PHH 20/25
Soo Eng left eye	UCVA =20/200	BSCVA = 20/50	PHH 20/25

Thanks!

Barbara S. Fant, Pharm.D.
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NYA 00148

4/1/02

IDE Patients having documented reduction in BCVA- Narrative explanation

Jacqueline Yeo- Previous to patient's OU LASIKprocedure patient had BCVA of 20/20 – OD, OS, OU. Two weeks after surgery she was best corrected to 20/25- OD, OS, OU. At the last visit on 1/21/02 after enhancement on both eyes she had BCVA of OD 20/25 + and OS 20/20-. We believe the reduction of BCVA was subjective error in patient responses.

Chris Wheeler- On 11/3/00 Mr. Wheeler had OD BCVA of 20/40 but on his latest visit 12/7/00 he had BCVA of 20/20. On 8/7/00 he had OS BCVA of 20/30 but on 12/4/00 he had BCVA of 20/25/+3. Mr. Wheeler had OD BCVA of 20/60 on 8/7/00 but as noted above his 12/7/00 BCVA was 20/20.

On 10/30/98 it was reported that Teresa Pavlin had a reduction of OS BCVA to 20/30 but on 5/26/00 she had BCVA of 20/25, we believe that this reduction was subjective error in patient reponses.

On 1/25/01 it was reported that Helen Onofrio had a reduction of her OD BCVA to 20/40. On 1/25/01 she had a refraction by another doctor in the practice who found BCVA of 20/25+ in her OD. We feel this might simply be doctor error in notation.

On 5/1/00 it was reported that Michael Nester had a reduction in his OS BCVA to 20/30 but yet on 3/26/01 his BCVA in his OS was 20/20-. We feel this might have been subjective error in patient responses.

On June 18, 1999 it was reported that Meghan Hoerner had a reduction in her OS BCVA to 20/30 but on 6/26/99 her BCVA in the OS was 20/25+1 and was 20/20 on 7/14/00. We believe this must be subjective error in patient responses.

On 3/4/99 it was reported by a comanaging doctor that **Colette Harlan** had a reduction in her BCVA OS to 20/40. On 5/6/99 Ms. Harlan was in our office and had OS BCVA of 20/20 therefore this reduction must have either been doctor transcription error or a subjective error in patient responses.

On 4/21/01 Eleanor Forstater had a reduction in her OD BCVA to 20/30 –2 but on 3/9/02 her OD BCVA was 20/25 +3. We feel this must have been subjective error in patient responses.

On 9/30/99 it was reported that Soo Eng had a reduction of BCVA in her OD to 20/60. Her preoperative BCVA was 20/30 and on 8/31/01 her OD BCVA was 20/25. This must have been subjective error in patient responses.

On 1/19/00 it was reported by a comanaging doctor that **Bruce Dizengoff** had a reduction in his OS BCVA to 20/30. In our office on 2/1/01 Mr. Dizengoff's OS BCVA was reported as 20/20-, this could have been doctor transcription error or subjective error in patient responses.

On 9/11/00 Pierre DeMauriac had a reported reduction in his OS BCVA to 20/30. On 1/22/01 Mr. DeMauriac's OS BCVA was 20/20+, therefore we believe this reduction in BCVA could have been technician error (technician did the refraction) or subjective error in patient responses since there was not a decrease in BCVA before or after the 9/1100 visit.

On June 29, 1998 there was a reported reduction in Raymond Bogdan's OS BCVA to 20/30 but on 10/5/00 his BCVA was 20/20. We feel there was possibly subjective error in patient responses on June 29,1998.

On June 29, 1998 and August 31, 1998 it was reported that John Welty had a reduction of his OD BCVA to 20/30. On A[illegible] Mr. Welty was examined and his BCVA was found to be 20/25 +2 in his OD therefore we feel this must have been subjective error in patient responses that led to the report of reduced OD BCVA.

On 12/21/00 it was reported that Al Pagnell had a reduction in his OS BCVA to 20/30 but at his last visit with us his OS BCVA was 20/20 so we feel that this reduction must have been subjective error in patient responses.

On 2/21/01 it was reported that Regina Albert had a reduction in her OS BCVA to 20/25 and on 1/8/01 her OD to 20/25. [illegible] visit to our office her BCVA in her OD was 20/20 and her OS was 20/20. Therefore we feel this must have been subjective error in patient responses.

On 2/15/00 it was reported that Linda Aaron had a reduction in her OS BCVA to 20/60 at a comanaging doctor" office. [illegible] visited our office and we found her OS BCVA to be 20/20 so we feel this might have been doctor transcription error or subjective error in patient responses since before or after 2/15/00 there was no dramatic reduction in BCVA.

On 4/4/98, 7/8/98 and 8/5/98 it was noted that Keith Wills had a reduction in his OD BCVA to 20/40. On 6/12.99 [illegible] OD BCVA of 20/25 + so feel this might have been subjective error in patient responses during the previous visits.

On January 4, 2001 it was reported that Yer Vang had a reduction of his OD BCVA to 20/25 from 20/15. This may have been a result of a small central island OD

On 11/19/98, 3/13/99 and 7/22/99 it was reported that John Tumolo had a reduction in his OD BCVA to 20/30. We feel [illegible] as a result of an approximately 1mm inferior temporal decentration in ablation.

On 3/16/00 and 10/25/00 it was reported that Daniel Paige had a reduction in his OD BCVA to 20/30. We feel this might have been as a result of a small central island.

On 7/19/01 it was reported that [illegible] Angstadt had a reduction in her OD BCVA to 20/30. We feel this might have been as a result of a small central island.

BSCVA To Check	PreopBSCVA	Last	First	Eye	F/UpDate	SxID	SchVisitID	VASC	RXsphere	RXCyl	RXAxis	BCVA
>20/40, check pre and post BSCVA	20	Aaron	Linda	OS	15-Feb-00	1236	6 Month	100	0.00	-1.75	170	60
check pre and post BSCVA	15	Albert	Regina	OD	08-Jan-01	1022	18 Month	25	1.25	-0.75	158	25
check pre and post BSCVA	15	Albert	Regina	OS	21-Feb-01	1021	18 Month	30	-0.50	-0.50	65	25
check pre and post BSCVA	20	Angstadt	Patricia	OD	19-Jul-01	1714	6 Month	30	0.50	-0.75	150	30
check pre and post BSCVA	20	Bagnoli	Al	OS	21-Dec-00	1529	6 Month	70	-2.25	-0.50	90	30
check pre and post BSCVA	20	Bogdan	Raymond	OS	29-Jun-98	275	9 Month	100	6.50	-1.25	120	30
check pre and post BSCVA	20	Chung	Suk Ling	OD	21-Dec-00	1457	6 Month	200	-2.25	-0.25	157	40
check pre and post BSCVA	20	DeMauriac	Pierre	OS	11-Sep-00	1019	12 Month	30	0.50	-1.50	107	30
check pre and post BSCVA	20	Dizengoff	Bruce	OS	19-Jan-00	1111	6 Month	80	-2.00	-0.50	15	30
>20/40, check pre and post BSCVA	30	Eng	Soo	OD	30-Sep-99	347	24 Month	70	0.25	-1.50	122	60
check pre and post BSCVA	20	Forstater	Eleanor	OD	21-Apr-01	1599	6 Month	30	-0.25	-0.75	143	30
check pre and post BSCVA	20	Harlan	Colette	OS	04-Mar-99	612	6 Month	70	-1.00	-0.50	90	40
check pre and post BSCVA	20	Hoerner	Meghan	OS	18-Jun-99	238	6 Month	60	-2.00	-0.25	45	30
check pre and post BSCVA	20	Nester	Michael	OS	01-May-00	928	12 Month	30	-0.75	-0.50	100	30
check pre and post BSCVA	25	Onofrio	Helen	OD	25-Jan-01	1544	6 Month	50	-1.00	-0.25	45	40
check pre and post BSCVA	20	Paige	Daniel	OD	16-Mar-00	1108	6 Month	30	-0.25	-1.00	105	30

BSCVA To Check	PreopBSCVA	Last	First	Eye	F/UpDate	SxID	SchVisitID	VASC	RXsphere	RXCyl	RXAxis	BCVA
check pre and post BSCVA	20	Paige	Daniel	OD	25-Oct-00	1108	12 Month	40	-0.75	0.00	0	30
check pre and post BSCVA	20	Paige	Daniel	OS	16-Mar-00	1107	6 Month	30	1.00	-0.25	130	30
check pre and post BSCVA	20	Paige	Daniel	OS	25-Oct-00	1107	12 Month	25	0.75	0.00	0	30
check pre and post BSCVA	20	Pavlin	Teresa	OS	30-Oct-98	218	9 Month	40	-1.50	-1.00	105	30
check pre and post BSCVA	20	Sawn	Walter	OS	17-Aug-98	407	6 Month	40	0.50	-0.25	90	30
check pre and post BSCVA	20	Tumolo	John	OD	19-Nov-98	261	12 Month	60	-1.00	-0.75	60	30
check pre and post BSCVA	20	Tumolo	John	OD	13-Mar-99	261	18 Month	30	-0.25	-0.50	65	30
check pre and post BSCVA	20	Tumolo	John	OD	22-Jul-99	261	24 Month	70	-0.50	-0.75	75	30
check pre and post BSCVA	15	Vang	Yer	OD	04-Jan-01	1284	12 Month	80	-1.50	-0.75	15	25
check pre and post BSCVA	20	Waddell	Lois	OD	08-Mar-00	826	6 Month	50	1.75	-1.25	135	30
check pre and post BSCVA	20	Waddell	Lois	OS	08-Mar-00	825	6 Month	70	-1.00	-0.50	15	40
check pre and post BSCVA	20	Welty	John	OD	29-Jun-98	325	6 Month	30	0.25	-0.75	95	30
check pre and post BSCVA	20	Welty	John	OD	31-Aug-98	325	9 Month	40	-0.25	-0.75	50	30
>20/40, check pre and post BSCVA	20	Wheeler	Chris	OD	07-Aug-00	1192	9 Month	200	0.00	-3.75	30	60
check pre and post BSCVA	20	Wheeler	Chris	OD	03-Nov-00	1192	12 Month	30	1.75	-2.25	45	40
check pre and post BSCVA	20	Wheeler	Chris	OS	07-Aug-00	1191	9 Month	100	0.25	-1.75	140	30

BSCVA To Check	PreopBSCVA	Last	First	Eye	F/UpDate	SxID	SchVisitID	VASC	RXsphere	RXCyl	RXAxis	BCVA	
heck pre and post SCVA	0	20 Wills	Keith	OD	04-Apr-98	278	6 Month	40	1.25	-2.00	110	40	✓
heck pre and post SCVA	0	20 Wills	Keith	OD	08-Jul-98	278	9 Month	100	2.75	-0.50	101	40	✓
heck pre and post SCVA	0	20 Wills	Keith	OD	05-Aug-98	278	12 Month	70	2.00	0.00	0	40	✓
heck pre and post SCVA	0	20 Wills	Keith	OS	04-Apr-98	277	6 Month	100	-1.50	-1.50	140	30	✓
heck pre and post SCVA	0	20 Wills	Keith	OS	01-Jun-98	277	9 Month	100	-1.25	-2.00	137	30	✓
heck pre and post SCVA	✓	20 Yeo	Jacqueline	OD	28-Jun-01	1499	12 Month	60	-4.00	-0.50	135	30	✓
heck pre and post SCVA	✓	20 Yeo	Jacqueline	OS	28-Jun-01	1500	12 Month	60	-1.75	-0.25	135	30	✓

2/26/00

HJN:

On top of the your refrigerator are the charts that have been pulled for reduction in BCVA, per Fant. I've attached to each chart the "rationalization" of decreased BCVA for each patient that improved after the date chosen by Fant. I couldn't "rationalize" for Angstadt, Chung, Paige, Sawn, Tumolo, Vang, Waddell and Wills. In addition I didn't develop a reason for BCVA decrease on any patients because of technical error (decentration, SPK, etc.). Please review my work and edit and return to my desk so that I might finalize this part of the chart review. I've forwarded the reasons for decrease to Fant to see if this is what she would need in an FDA audit.

Rich

IDE Patients having documented reduction in BCVA- Narrative explanation

Jacqueline Yeo- Previous to patient's OU LASIKprocedure patient had BCVA of 20/20 – OD, OS, OU. Two weeks after surgery she was best corrected to 20/25- OD, OS, OU. At the last visit on 1/21/02 after enhancement on both eyes she had BCVA of OD 20/25 + and OS 20/20-. We believe the reduction of BCVA was subjective error in patient responses.

Chris Wheeler- On 11/3/00 Mr. Wheeler had OD BCVA of 20/40 but on his latest visit 12/7/00 he had BCVA of 20/20. On 8/7/00 he had OS BCVA of 20/30 but on 12/4/00 he had BCVA of 20/25/+3. Mr. Wheeler had OD BCVA of 20/60 on 8/7/00 but as noted above his 12/7/00 BCVA was 20/20.

On 10/30/98 it was reported that **Teresa Pavlin** had a reduction of OS BCVA to 20/30 but on 5/26/00 she had BCVA of 20/25, we believe that this reduction was subjective error in patient reponses.

On 1/25/01 it was reported that **Helen Onofrio** had a reduction of her OD BCVA to 20/40. On 1/25/01 she had a refraction by another doctor in the practice who found BCVA of 20/25+ in her OD. We feel this might simply be doctor error in notation.

On 5/1/00 it was reported that **Michael Nester** had a reduction in his OS BCVA to 20/30 but yet on 3/26/01 his BCVA in his OS was 20/20-. We feel this might have been subjective error in patient responses.

On June 18, 1999 it was reported that **Meghan Hoerner** had a reduction in her OS BCVA to 20/30 but on 6/26/99 her BCVA in the OS was 20/25+1. We believe this must be subjective error in patient responses.

On 3/4/99 it was reported by a comanaging doctor that **Colette Harlan** had a reduction in her BCVA OS to 20/40. On 5/6/99 Ms. Harlan was in our office and had OS BCVA of 20/20 therefore this reduction must have either been doctor transcription error or a subjective error in patient responses.

On 4/21/01 **Eleanor Forstater** had a reduction in her OD BCVA to 20/30 –2 but on 3/9/02 her OD BCVA was 20/25 +3. We feel this must have been subjective error in patient responses.

On 9/30/99 it was reported that **Soo Eng** had a reduction of BCVA in her OD to 20/60. Her preoperative BCVA was 20/30 and on 8/31/01 her OD BCVA was 20/25. This must have been subjective error in patient responses.

On 1/19/00 it was reported by a comanaging doctor that **Bruce Dizengoff** had a reduction in his OS BCVA to 20/30. In our office on 2/1/01 Mr. Dizengoff's OS BCVA was reported as 20/20-, this could have been doctor transcription error or subjective error in patient responses.

On 9/11/00 Pierre DeMauriac had a reported reduction in his OS BCVA to 20/30. On 1/22/01 Mr. DeMauriac's OS BCVA of 20/20+, therefore we believe this reduction in BCVA could have been technician error (technician did the refraction) or subjective error in patient responses since there was not a decrease in BCVA before or after the 9/1100 visit.

On June 29, 1998 there was a reported reduction in Raymond Bogdan's OS BCVA to 20/30 but on 10/5/00 his BCVA was 20/20. We feel there was possibly subjective error in patient responses on June 29,1998.

On June 29, 1998 and August 31, 1998 it was reported that John Welty had a reduction of his OD BCVA to 20/30. On April 19,1999 Mr. Welty was examined and his BCVA was found to be 20/25 +2 in his OD therefore we feel this must have been subjective error in patient responses that led to the report of reduced OD BCVA. .

On 12/21/00 it was reported that Al Bagnoli had a reduction in his OS BCVA to 20/30 but at his last visit with us his OS BCVA was 20/20- so we feel that this reduction must have been subjective error in patient responses.

On 2/21/01 it was reported that Regina Albert had a reduction in her OS BCVA to 20/25 and on 1/8/01 her OD to 20/25. On the last visit to our office her BCVA in her OD was 20/20 and her OS was 20/20. Therefore we feel this must have been subjective error in patient responses.

On 2/15/00 it was reported that Linda Aaron had a reduction in her OS BCVA to 20/60 at a comanaging doctor'' office. On 2/21/00 she visited our office and we found her OS BCVA to be 20/20 so we feel this might have been doctor transcription error or subjective error in patient responses since before or after 2/15/00 there was no dramatic reduction in BCVA.

Nevyas Eye Associates Quality Manual

MANAGEMENT RESPONSIBILITY

Policy

The executive management at Nevyas Eye Associates, Inc. is ultimately responsible for implementing and maintaining the quality system. Executive management defines the quality policy and objectives, determines the organizational structure and responsibilities for quality related activities, and provides the necessary resources required to maintain the quality system. Management reviews the suitability and effectiveness of the quality system and objectives on a periodic basis.

Quality Policy

Executive management documents the quality policy and quality objectives. Nevyas Eye Associates, Inc. is committed to continuous measured quality improvement. All employees receive training on the quality policy and objectives when they are hired and at training sessions held on a periodic basis.

Organization, Responsibility and Authority

The interrelationship of personnel who manage, perform, and verify work affecting quality is outlined in the organizational chart in this section. All personnel at Nevyas Eye Associates are responsible for maintaining and supporting the quality system. Specific responsibilities are explained in functional job descriptions.

Resources

Executive management is responsible for providing the necessary resources to implement and maintain the quality system. This includes assigning trained personnel to activities affecting product quality and verification activities, including contracted internal quality audits.

Management Representative

Nevyas Eye Associates has appointed the Director of Inter-professional Relations (IR) as the management representative. The management representative has the authority and responsibility to ensure that the quality system is established, implemented, maintained; and complies with 21 CFR Part 820, as applicable and appropriate. The management representative is responsible for reporting on the performance of the quality system to Dr. Herbert Nevyas.

Management Review

- Executive management meets annually to review the quality system. Management reviews may be held more frequently when necessary. The review is coordinated by the Director of IR.

- Minutes of the review, including the date and individuals present are kept on file.
- Reviews are attended by at least Dr. Nevyas and the Director of IR.
- The agenda is prepared by the Management Representative. The suitability and effectiveness of the quality system is assessed by reviewing the following: quality performance data, internal quality audit program, customer response, regulatory issues, corrective and preventive actions, the quality policy, and the effectiveness of the quality system.
- Other information may be presented at the discretion of the Director of IR.

QUALITY SYSTEM

Policy

Nevyas Eye Associates maintains a documented quality system designed to fulfill the requirements of the Quality System Regulation. The quality system is documented in this quality manual, standard operating procedures, master device records, device history records, parts lists, and equipment operating procedures. The quality system defines the control of design information, incoming materials, production processes, in process testing, and testing / inspections.

Quality System Documentation

- The quality system is defined in the quality manual, standard operating procedures, device master record, design history file, parts lists, and equipment operating procedures.
- These documents define a quality system that complies with the Quality System Regulation as applicable to Nevyas Eye Associates. Document Control explains the purpose of these documents and the methods for controlling their distribution and use.

Quality System Implementation

- All personnel who manage, perform, and verify work affecting quality are responsible for implementing the quality system. The Director of IR is responsible for coordinating, monitoring, and auditing the system.

INTERNAL QUALITY AUDITS

Policy

Internal audits are conducted. All areas of the Quality System are audited at least once per year. Internal audits are used to measure compliance to and the effectiveness of the Quality System. Audits are scheduled on the basis of status and

importance of the individual areas. Audits are conducted by personnel independent of the activity being audited, i.e. contracted to a third party.

Planning and Scheduling

- The internal audit plan and schedule is established by the Director of IR. All areas of the Quality System are audited at least once per year. These audits are divided up by functional areas. The audit schedule can be revised and updated at any time in order to focus on important or deficient areas, as applicable.

Auditors

- All audits are conducted by an outside consultant to Nevyas Eye Associates.

Conducting the Audit

- Objective evidence is compiled to show the level of compliance to the documented quality system and to determine the effectiveness of the quality system.

- The audit report contains the dates of the audit, the personnel and areas involved, and documentation of the non-conformances and observations found. Corrective action and preventive action requests are issued for all non-conformances and presented to the director and supervisor of the area in which they occurred. Auditors try to minimize disruptions to the audited activities.

Corrective Action and Follow Up Activities

- The Director of IR responds to the corrective action and preventive action requests and signs the audit report. The auditor and auditee determine acceptable due dates for each corrective action.

- Corrective action is completed in a timely manner. Implementation and effectiveness of the corrective action is verified by a follow up audit, where necessary.

- All audit reports are presented for management review. Audit reports are filed in a safe and secure manner.

TRAINING

Policy

Human resource, quality system and safety training is given to all employees. Individual Managers and Supervisors are responsible for training each employee in their job functions. Personnel are qualified based on education, training, and experience. Training files are maintained for all personnel as a quality system record.

Identification of Training Needs

- The Director of IR determines the general training needs of all employees. Employees are qualified based on education, training, and experience.
- The Director of IR is responsible for determining the specific training needs of the personnel in their areas and for establishing departmental training programs.
- Supervisors and individuals are responsible for job specific training in their areas.
- Training needs are also identified from nonconforming product reports, corrective and preventive action requests, complaints and other sources of quality data.

Training Records

- The Director of IR maintains training files for all of the employees. Training files contain documentation of qualifications, on the job training, and outside training courses completed.

DESIGN CONTROL

Note: This quality manual supports the one Nevyas laser device on site. The device is presently in use and another device being designed, constructed, etc. is not anticipated. Therefore, these are the only sections of the Design Controls GMPs that are applicable:

Design Validation

- Design validation consists of performance testing intended to demonstrate that the product specifications meet the final intended use of the device. Validation is conducted using production devices or their equivalents under defined operating conditions. Software validation is required.
- Validation testing is conducted under actual or simulated use conditions that will require clinical trials.

Design Approval and Release

- Design approval and release consists of officially documenting the review board's concurrence that changes to product design meet all defined requirements and may be released for use by Nevyas Eye Associates as appropriate.

Design Changes

- Changes during the design process are reviewed and approved by Dr. Nevyas and the Director of IR before they are implemented.
- The design requirements are modified to incorporate changes. Design changes are verified and validated when appropriate.

Design History File

- The Design History File (DHF) is a compilation of written documents and records, which describe the design history of a finished device. A DHF will be compiled and maintained for this device. The Director of IR maintains the DHF through the history of the device.
- The DHF demonstrates that the device was developed according to plan.

DOCUMENT AND DATA CONTROL

Policy

All documents are reviewed and approved before they are issued. Documents and document changes are approved by designated individuals. Documents are always available in the areas where they are used. Obsolete documents are removed from points of use. A master list of approved documents is maintained in document control. A history of document changes is kept as part of each document

Quality System Documentation

At Nevyas Eye Associates quality system documentation consists of the following types of documents:
Quality Manual, Device Master Records, Standard Operating Procedures, Quality Procedures, Component Specifications, Parts Lists, Labeling Specifications, Brochure Specifications, Standards, Design History File and other technical reference materials

Document and Data Control

- New documents and document changes may be initiated by all employees at Nevyas. Documents are only issued by document control. Documents are reviewed and approved by designated individuals/areas before they are issued. Documents are available in the areas where they will be used. Obsolete documents are removed promptly from all points of use. Document control maintains copies of obsolete and superseded documents. These documents are marked and segregated from approved documents.

- A master list of all documents is maintained in document control. This list identifies the current revision status of all documents.

- Electronic documents and databases are backed up on a regular basis by Nevyas Eye Associates.

Document and Data Changes

- Changes to documents are reviewed and approved by the same functions that reviewed and approved the original document. Validations, justifications, and pertinent background information are circulated with the document during the approval process.
- Changes to documents are indicated on the cover sheet and in the attached description of change history. Cover sheets to documents contain the current changes to the document, the change author, the effective date of the change, and the signatures of the approving individuals.

PURCHASING CONTROLS

Policy

Nevyas Eye Associates evaluates the capability and quality systems of its suppliers and subcontractors and purchases only from the approved suppliers. Supplier performance is monitored. Purchasing documents specify the requirements of purchased material and are reviewed and approved before orders are placed. The Director of IR is ultimately responsible for ensuring that all purchased materials and services that have an impact on the quality of finished products and services conform to specified requirements.

Evaluation of Suppliers

- The Director of IR is responsible for approving suppliers/subcontractors. Suppliers are selected based on defined criteria related to a supplier's/subcontractor's ability to meet Nevyas' requirements for quality, cost, and delivery. Critical materials and services may only be purchased from suppliers on the approved component specification.

- Purchasing maintains a record of each supplier's aberrant performance and capability to meet Nevyas Eye Associates requirements.

- Suppliers with inadequate performance are requested to implement corrective action and may be removed as approved suppliers if there is no improvement.

Purchasing Data

- The Director of IR is responsible for ensuring that purchase orders are reviewed and approved for adequacy of specified requirements prior to ordering, i.e., supplier/subcontractor is approved, product is defined, quality requirements are stated, packaging and delivery requirements are specified.

- Buyers are responsible for ensuring that purchasing documents contain data clearly and completely describing the product ordered. In cases where the purchase order is not sent to the customer or when the purchasing information is sent via fax, the buyer verifies that all information is correct before it is sent.

- Copies of purchasing documents are retained to allow traceability to the raw materials and components / parts.

Verification of Purchased Product

- It is the policy at Nevyas Eye Associates, where specified in the contract, that the purchaser or his representative shall be afforded the right to verify at the source or upon receipt that purchased product conforms to specified requirements. Verification by the purchaser shall not absolve the supplier of the responsibility to provide acceptable product nor shall it preclude subsequent rejection.

- Whenever possible, it is specified that suppliers/subcontractors agree to notify Nevyas Eye Associates of any changes to purchased materials, so that the affect of the changes on finished product quality may be determined.

PRODUCT IDENTIFICATION & TRACEABILITY

Policy

Incoming materials and components are assigned unique numbers from an approved component specification or off-the-shelf catalogue when they are received. When assemblies, devices and components are made they are assigned a unique Nevyas Eye Associates lot number. Nevyas Eye Associates keeps Design History changes which track what materials are used in each lot.

Product Identification

- Materials and components that become part of Nevyas Eye Associate's device have a unique number from an approved component specification when they are received. This identification number and the manufacturers lot number are used to identify materials utilized in production processes.

- The Nevyas device is identified by name and serial number.

- Release status is controlled.

Traceability

- Records are maintained to track all materials, components, testing, inspection, environmental conditions, and personnel involved in the maintenance and servicing of the device.

PROCESS CONTROL

Device repair, preventive maintenance and part replacements are carried out under controlled conditions using documented procedures. Device procedures contain criteria for workmanship. Device testing equipment is calibrated and maintained to ensure functionality. Personnel are made aware of practices that could affect safety and product quality. Processes that can not be fully verified by testing and inspection are validated. Software used in process control and the device is validated.

Process Controls (Servicing, Maintenance and Repair only)

- Dr. Nevyas and the Director of IR are responsible for ensuring that these above processes are identified, planned, and executed under controlled conditions.
- Written procedures and instructions are used to ensure that processes that have a direct affect on the device's quality are carried out in a uniform manner. When it becomes necessary to deviate from procedures, all deviations are approved before any design activities are performed.
- These repair, replacement and preventive maintenance processes are controlled and monitored. In-process testing is performed at key points before the device is released for continued use by Nevyas Eye Associates.

Production and Process Changes

- Changes to methods, procedures, and specifications are reviewed and approved by the same people who initially approved the process before incorporation into production processes. Verification and validation are performed when changes are made to production processes, when necessary.
- When temporary changes to processes or specifications are required, they are documented and approved on a deviation request.

Environmental Controls

- Environmental conditions are monitored in areas where they could adversely affect device quality. There are no environmental requirements for this device.

Personnel

- Personnel are trained in their job functions and made aware of personal practices, which could affect product quality and / or personnel safety.

Contamination Control

- The Director of IR is responsible for ensuring that procedures are written and followed for establishing and maintaining sanitation and cleaning programs for facilities and equipment used in support of this device.

Buildings

- The Director of IR is responsible for ensuring that there is adequate space and a suitable design of work areas to prevent mix-ups of incoming parts and gases.

Equipment

- Equipment is regularly maintained and calibrated. The Director of IR assigns a maintenance and calibration schedule for the device.
- The Director of IR maintains files of all calibration and maintenance activities. Equipment is regularly inspected to assure that preventive maintenance has been completed. The device is calibrated prior to each use.

Process Validation

- All equipment that affect the quality of Nevyas Eye Associates device are verified and / or validated to ensure proper control and function. The device is calibrated prior to each use.
- Design validation of device changes is achieved as necessary. A new design is not released for use until it has been fully verified and validated.
- When computer software is used in production processes, it is validated according to its intended use. Changes to software are validated before they are used.
- All validations are carried out according to a validation protocol that is approved before use. All validation results and activities are documented in a validation report.

INSPECTION, MEASURING & TEST EQUIPMENT

Policy

Equipment is selected based upon the measurement and accuracy needs the device. All calibration standards used for equipment are traceable to national standards

(NIST). The calibration and maintenance status is clearly indicated on each piece of equipment. All employees are responsible for removing past due and uncalibrated equipment from service and bringing it to the attention of the Director of IR. The location and use of calibrated equipment is always controlled.

Control of Equipment

- The Director of IR is responsible for ensuring that all inspection, measuring, and test equipment used in testing is controlled, calibrated, and maintained according to procedures.
- Employees in the production, quality control, and product development areas do not use uncalibrated or past due equipment.
- Each piece of equipment has its own documented procedure and schedule for certifying its accuracy when used in the manufacturing process. "Uncalibrated" and "maintenance only" as needed equipment is clearly labeled. Inspection, measuring, and test equipment used to perform functional testing is calibrated regularly.
- The calibration /maintenance log documents the chronological history of all calibration and preventive maintenance activities and is maintained by the Director of IR.
- The date the calibration/maintenance was performed, the person who performed it, and the next due date is indicated on or near each piece of equipment.
- The Nevyas device is calibrated prior to each use.

Measurement Identification and Selection of Equipment

- Equipment is selected based on the measurement and accuracy needs of the device. Equipment is verified and validated to ensure that it is suitable for its intended use.

Equipment Calibration and Maintenance

- All equipment is marked or tagged with its assigned asset number and is labeled with its calibration and maintenance status.
- Internal standards that are utilized to verify the accuracy of inspection instruments are regularly calibrated by outside labs. When possible, calibration standards are traceable to the National Institute of Standards and Technology (NIST). All inspection, measuring, and test equipment that is not in current calibration is removed from the device area (s). New equipment or equipment with a past due calibration date is segregated to prevent use until the calibration has been completed.