

✓

Special Instructions: _____



Transmittal Sheet "From" Legal Unit

TO: <input type="checkbox"/> Investigation <input checked="" type="checkbox"/> Program <input type="checkbox"/> MC		RCM: UBER OI	MC: HEYE
RESPONDENT'S LAST NAME: BIANCHI		FIRST: ELIZABETH	MIDDLE INITIAL: A.
CASE NUMBER: 02-12-0019 MD	STAFF ATTORNEY: FELLY	DATE LEGAL FORWARDED: 8-27-03	
PRIORITY: <input type="checkbox"/> 1-HIGH <input checked="" type="checkbox"/> 2-MEDIUM <input type="checkbox"/> 3-LOW			
REASON FOR FORWARDING: <input type="checkbox"/> SEND TO REVIEWING COMMISSION MEMBER <input type="checkbox"/> FURTHER INVESTIGATION <input type="checkbox"/> TRANSFERRED TO AAG			
CASE COMPLETION REASON: <input checked="" type="checkbox"/> CLOSED, NCFA <input type="checkbox"/> STID ACCEPTED <input type="checkbox"/> LICENSE APPLICATION GRANTED <input type="checkbox"/> AGREED ORDER ACCEPTED <input type="checkbox"/> DEFAULT ORDER <input type="checkbox"/> FINAL ORDER ISSUED			

H:\data\doc\forms\transmittalfrom legal.doc

Respondent: Bianchi, Elizabeth A.
Case #: 02-12-0019MD
IRP Presenter: Crowell

MEDICAL QUALITY ASSURANCE COMMISSION
Initial Review Panel
Case Assignment Transmittal

Date: JUN 24 2003

To: ☒ Legal Shelly, Staff Attorney
☐ Investigations
☐ Licensing Manager
☐ Medical Consultant
☐ Case Coordinator
☐ Compliance Officer

The following action was ordered by the Initial Review Panel at the JUN 24 2003 meeting:

<input type="checkbox"/> Close "no cause for action"	<input type="checkbox"/> Close with letter of concern
<input type="checkbox"/> Close "no jurisdiction"	<input type="checkbox"/> Close no jurisdiction. To local Medical Society
<input type="checkbox"/> Administrative closure	<input type="checkbox"/> Expert Review by _____
<input checked="" type="checkbox"/> To RCM _____	<input type="checkbox"/> Legal Review
<input type="checkbox"/> Close "below threshold"	

☐ Further investigation concerning _____

☐ Practice review with emphasis on _____

☐ Other _____

Special Instructions: _____

Hamilton, Cindy

From: Hamilton, Cindy
Sent: Tuesday, May 27, 2003 2:52 PM
To: Creighton, Vicki
Cc: Smith, James H
Subject: Case No. 2002-12-0019MD

Vicki:

During investigation of case no. 2002-12-0019MD, Tom Heafey discovered the identity of the formerly unknown doctor.

Therefore, please request that Tim Boorman move case no. 2002-12-0019MD

from: Medical, Unknown **to:** Bianchi, Elizabeth A. MD00035207

Thanks!

Cindy

Cynthia R. Hamilton, Investigations

WA ST Dept. of Health; Medical Quality Assurance Commission
(310 Israel Road SE); PO Box 47866; Olympia, WA 98504-7866

Telephone: (360) 236-4805 *** E-mail: cynthia.hamilton@doh.wa.gov
Fax: (360) 586-4573 *** Web Page: <http://www.doh.wa.gov/medical/default.htm>

*"The Department of Health Works to Protect and
Improve the Health of People in Washington State"*

**DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION - SECTION 5**

INTAKE SHEET

Respondent Information

Case No: 02-12-0019MD

Case Opened: 12/10/2002

Name: Elizabeth A. Bianchi, MD

Lic/Cert/Reg No: MD00035207

Issued: 7/14/1997

Address: E 10808 46th

D.O.B.: 7/14/1951

Expires: 7/14/2003

Soc Sec No: 1 - DOH Licen...

Spokane, WA 99206

School Attended: U of FL; Gainesville, FL

Year Completed: 1995

Specialty: Family Practice

Board Certified: Yes

Complainant Information

Name: MD Confidential

Address: _____

Companion Case Information (other Respondent)

Previous Case Information (same respondent)

***Steps**

A=Assess

RM = Reviewing Member

S=Settlement

I=Investigating

LD=Legal Drafting

LP=Legal Prehearing

LR=Legal Review

LS = Legal Service

RAG=Legal Support

F=Final Action

RPT002

05/27/2003

Page 1 of 1

MEDICAL BOARD
jhs0303
INDIVIDUAL NAME
LAST BIANCHI
FIRST ELIZABETH
MIDDLE A

RESIDENCE INFORMATION
E 10808 46TH
SPOKANE WA 99206

PHONE: () - COUNTY: 32
() - LGL ST: WA

NOTES

ASSESSMENT SYSTEMS, INC.
REAL SYSTEM
(JR, SR, III)

05-27-03
01:05:38 PM
V2.5.74
REFERENCE # MD00035207
SOC SEC NUM 1 - DOH Licensee Soc...

+--ADDITIONAL INFORMATION--+

SEX M =	MARRIED Y =
OTHER NAME	
CORP. OFFICER	=
TRUST ACCOUNT	
BIRTH PLACE CALIFORNIA	
DATE 07-14-1951	
SCHOOL CODE 011.03	
CE UNITS	0.00 REQD BY 07-14-2005

+--+

+--+

CURRENT STATUS: A D	EXPIRATION DATE: 07-14-2003	FIRST ISSUE DATE: 07-14-1997
RENEWAL STATUS: M	LAST ACTIVE DATE: - -	LAST RENEWAL DATE: 06-04-2001
COMPLAINTS O/C: 0/0	AUTHORITY:	

+--+

1GO BACK 2NAM&ADDR 3EDUCATE 4LIC FUNC 5INVESTG 6 7OTHR DAT 8EXTD NOT

2002-12-0019MD

12-10-2002

22/10

Prd Cert - Family Practice *Aiding and abetting*
unlicensed practice
1995/11 of FL; Gainesville, FL

formerly:

Medical, Unknown

Complainant

Confidential

1276649

American Medical Association

Physicians dedicated to the health of America

Division of Survey and Data Resources
515 North State Street
Chicago, Illinois 60610
<http://www.ama-assn.org/amaprofiles>



AMA Physician Profile

Name and Mailing Address:

ELIZABETH ANN BIANCHI MD
10808 E 46TH AVE
SPOKANE WA 99206-9468

Primary Office Address:

2814 S GRAND BLVD
SPOKANE WA 99203-2528

Phone: 1-509-747-2902

Birthdate: 07/14/1951

Birthplace: RIVERSIDE, CA UNITED STATES OF AMERICA

Physician's Major Professional Activity: OFFICE BASED PRACTICE

Practice Specialties Self Designated by the Physician:

Primary Specialty: FAMILY PRACTICE

Secondary Specialty: UNSPECIFIED

AMA membership: NON MEMBER

Following Data Provided by the Primary Sources

Medical School:

UNIV OF FL COLL OF MED, GAINESVILLE FL 32610 (VERIFIED)

Reported Year of Graduation: 1995 (VERIFIED)

Current and/or Prior Medical Training Programs Accredited by the Accreditation Council for Graduate Medical Education (ACGME):

Institution: INLAND EMPIRE HP SERV ASSOC

Specialty : FAMILY PRACTICE

State: WASHINGTON

. 06/1995 - 06/1998
(VERIFIED)

American Medical Association

Physicians dedicated to the health of America

Division of Survey and Data Resources
515 North State Street
Chicago, Illinois 60610
<http://www.ama-assn.org/amaprofiles>



AMA Physician Profile

License(s): State	MD/ DO	Date Granted	Expiration Date	Status	License Type	Last Reported
WASHINGTON	MD	07/14/1997	07/14/2003	ACTIVE	UNLIMITED	03/06/2003

Note: When the specific month and day are unknown, the date will display the default value of "01." Not all licensing boards maintain or provide full date values. Please contact the appropriate licensing board directly for this information.

ECFMG Certification:

Applicant Number:

Note: The Educational Commission for Foreign Medical Graduates (ECFMG) applicant identification number does not imply current ECFMG certification status. To verify ECFMG status, contact the ECFMG Certification Verification Service in writing at P.O. Box 13679, Philadelphia, PA 19101.

Federal Drug Enforcement Administration:

FEDERAL DEA REGISTRATION INFORMATION WAS LAST REPORTED TO THE AMA ON 03/04/2003.
DEA REGISTRATION IS VALID THROUGH 07/31/2004.

Note: Many states require their own controlled substances registration/license.
Please check with your state licensing authority as the AMA does not maintain this information.

Specialty Board Certification(s):

Specialty Board Certification(s) by one or more of the 24 boards recognized by the American Board of Medical Specialties (ABMS) and the American Medical Association (AMA) through the Liaison Committee on Specialty Boards, as reported by the ABMS:

Certifying Board: AMERICAN BOARD OF FAMILY PRACTICE

Certificate: FAMILY PRACTICE

Certificate Type: GENERAL

Effective: 07/01/1998 **Expiration:** 12/01/2005

Last Reported: 01/16/2003 **INITIAL**

Note: For certification dates, a default value of "01" appears in the month field if data was not provided to AMA. Please contact the appropriate specialty board directly for this information.

Medicare/Medicaid Sanction(s):

TO DATE, THERE HAVE BEEN NO SUCH SANCTIONS REPORTED TO THE AMA BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.

Other Federal Sanction(s):

TO DATE, THERE HAVE BEEN NO FEDERAL SANCTIONS REPORTED TO THE AMA BY ANY BRANCH OF THE US MILITARY, THE VETERAN'S ADMINISTRATION OR THE US PUBLIC HEALTH SERVICE.

American Medical Association

Physicians dedicated to the health of America

Division of Survey and Data Resources
515 North State Street
Chicago, Illinois 60610
<http://www.ama-assn.org/amaprofiles>



AMA Physician Profile

Additional Information:

TO DATE, THERE IS NO ADDITIONAL INFORMATION FOR THIS PHYSICIAN ON FILE.

The content of the AMA Physician Profile is intended to assist with credentialing. Appropriate use of the AMA Physician Masterfile data contained on this Profile by an organization would meet the primary source verification requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American Accreditation HealthCare Commission/URAC. The Physician Masterfile meets the National Committee for Quality Assurance (NCQA) standards for verification of medical education, residency training, board certification, DEA status, and Medicare/Medicaid sanctions.

If you note any discrepancies, please mark them on a copy of the profile and mail or fax to:

Division of Survey and Data Resources
Attn: Physician Profile Unit
515 N. State Street
Chicago, IL 60610
312 464-5199
312 464-5900 (fax)

**INITIAL REVIEW PANEL
CASE PRESENTATION**

Case Number:
02-12-0019MD

MD/PA	_____
AGE	_____
FOP	_____
TOM	_____
C/C	_____, _____, _____
Disp	_____

Date: May 29, 2003
Presented by: Bill N. Crowell, PA-C

Respondent:	Elizabeth A. Bianchi, MD	Spokane County
--------------------	---------------------------------	-----------------------

Complainant:	Confidential
---------------------	--------------

CASE SUMMARY

The Respondent: Is a 51-year-old Board Certified Family Practice physician, who has been licensed in the State of Washington since July 14, 1997.

The Complainant: Confidential

Malpractice Settlement: N/A

The Complaint: Possible aiding or abetting unlicensed practice.

Complaint Review: On December 10, 2002, the MQAC Medical Consultant received a telephone call regarding a hair removal business advertising itself as removing not only hair, but also performing treatment of vascular lesions, i.e., leg veins, and superficial skin pigmentation problems. This was accomplished through the use of a pulsed light unit called an "Aurora" and the personnel performing the treatments were reportedly not medically licensed, although they may have been trained by the company that manufactured the machine. It was also alleged that while there may have been some medical supervision, no physician was on site.

The original complaint had been opened as an unknown physician. Upon visiting the business, named Nuvo Laser Skin Clinic, which is located in a large shopping mall in eastern Washington, the investigator learned it was managed by a Mr. JG. In an advertisement from a local newspaper with a large circulation, the offered services at the clinic included Botox injections, photo facials and photo rejuvenation to remove age spots and other blemishes, laser hair removal, micro dermabrasion, spider vein therapy, and tattoo removal. The MQAC Investigator learned at that time that the Respondent was the medical director of not only this clinic but also another in Seattle, and that the Seattle clinic had recently undergone an investigation by the Unlicensed Program of the Department of Health.

Review of that investigation reveals that a complaint had been received on September 4, 2002, from a patient who had undergone hair removal treatment from a different Respondent, a cosmetologist, and sustained blisters and redness of his left cheek. Two other complaints had also been received against two other cosmetologist, although they related more to technique rather than an adverse outcome or patient harm. During the investigation, it was learned that the clinic did have a medical director, although it was not the Respondent. However, during the course of the investigation, and after the medical director was made aware there was an

ongoing investigation of the clinic, he resigned. The medical director reported he had been approached three years prior by the owners of the clinic to help the company finance several lasers, under the impression that it would be easier for the company to obtain better financing of a laser with a physician listed as a member of the staff.

The medical director noted he was paid \$500 a month to compensate him for the risk of putting his name on the lease, and that he had never been involved in the planning or set up of the day-to-day operations of the clinic. He did note that he had ordered, per the request of the clinic manager, topical Lidocaine 5% for the clinic. The medical director also pointed out that it was his impression that the laser work was to be performed by registered nurses. He also reported that he had only been called to the clinic once in the several years he had been listed as the medical director, and had not been in the clinic for the past six months. It is noted the medical director recently completed a Board Order.

Following the medical director's resignation in December 2002, the clinic obtained the services of the Respondent on January 15, 2003. The Respondent is now acting as the medical director for both clinics.

The Respondent replies that as the medical director of for NUVO, she is responsible in ensuring that client safety and supervision of procedures performed by the staff, including assessment of dermatological conditions, and training and use of the equipment for treatments. The Respondent notes she is available by phone and in person, if needed, for any medically related questions at either the Spokane or Seattle clinic.

The Respondent goes on to say the only invasive procedures she performs is Botox injections and sclerotherapy for small leg veins/telangiectasias. A copy of her training in Botox and sclerotherapy was provided, as well as additional training in the use of lasers. In answering the MQAC Investigator's question regarding what medications are used by her, the Respondent noted she only used Botox and 0.2 % or 0.3% Sodium Tetradecyl Sulfate for sclerotherapy. On a rare occasion, the Respondent notes she has written a prescription for 2% lidocaine gel for patients who experience difficulty in tolerating hair removal or *Photo Facial* treatments. The Respondent adds that she personally sees these patients in the clinic.

In continuing to answer the MQAC Investigator's question regarding how she supervises the operation in both the Seattle and Spokane clinics, the Respondent answers by saying she is available by phone or in person twenty-four hours a day, seven days a week. That if an emergent condition was to arise, 911 would be called and the patient transferred to the nearest hospital. For other non-emergent conditions, the client would be scheduled to see her.

The Respondent states there is now an RN at the Seattle office and she could arrange to fly to Seattle from Spokane if the need should arise. The Respondent goes on to say she provides routine services to the Spokane clinic and travels to Seattle at least monthly to communicate with the Seattle staff and management regarding medically related topics. In addition, the Respondent notes she has developed a relationship with a local dermatologist to assist her with any questions or referrals.

The Respondent notes her experience in this field of medicine includes elective rotations through plastic and dermatology and that she has taken post graduate training in FotoFacial (IPL) technology, extensive workshops in Botox injections and sclerotherapy with a noted physician in Boise, ID. The Respondent also notes that she completed a two day Aesthetics workshop and seminar from the National Procedures Institute for procedures including cosmetic patient evaluation, Botox and collagen injection, skin resurfacing, lasers, hair removal, and

office surgery. In addition, the Respondent notes that she continues to stay current with cosmetically related dermatology literature.

The Respondent goes on to say that the staff is well trained to distinguish when treatment is not indicated and what contradictions exist for cosmetic procedures, noting that they are outlined in the *Training and Treatment Manual*. The Respondent adds that she is available to see and or discuss any patients who may have a condition that requires evaluation. In addition, the Respondent notes that all patients fill out a general medical history and are evaluated prior to the procedure.

The Respondent, when asked the question by the MQAC Investigator, how many times she had been contacted by phone, related that she seldom gets contacted regarding a patient concern or injury, adding that the procedures are very safe, that the clients are given informed consent, and that all questions and expectations are addressed.

The Respondent answered the question if she had a written contract with the clinic by replying she did not, that she is compensated by salary, and has no ownership in the company.

A number of patient handout sheets and instructions were included with the Respondent's statement, regarding the different treatments, complications, frequency of treatments, and telephone numbers to call if problems were incurred. The Spokane clinic has 12 employees, including aestheticians, receptionists, office manager, and the Respondent.

Prior Cases: **None**

**DEPARTMENT OF HEALTH
HEALTH PROFESSIONS SECTION 5
INVESTIGATIONS UNIT**

CONFIDENTIAL INVESTIGATIVE REPORT

**PREPARED FOR THE
MEDICAL QUALITY ASSURANCE COMMISSION**

CASE # 2002-12-0019MD

Respondent:

Elizabeth Bianchi, MD (Unknown MD)
10808 46th Avenue
Spokane, WA 99206

Attorney:

None provided

H. (509) 926-8462 Cell: (509) 995-0368

Complainant:

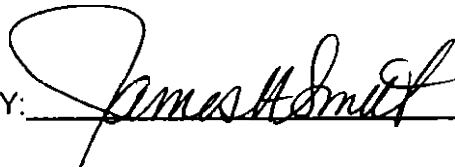
Confidential

Attorney:

None Provided

Investigative Case File completed by Investigator: T.R. Heafey on May 23, 2003

APPROVED BY: _____



DATE: _____

5/27/03

GENERAL CASE SUMMARY

COMPLAINT / ALLEGATIONS: A confidential complainant contacted the WA State Department of Health on 12-10-2002 concerned about a hair removal business at the Spokane Valley Mall that offers photo rejuvenation through the use of a pulsed light unit called "Aurora" manufactured by Syneron. Reportedly, none of the personnel are medically licensed but have been trained to operate the Aurora machines by the company.

CASE REVIEW: *Nuvo* of Spokane is located in the Spokane Valley Mall, managed by Jeff Gelnette. In addition to informational material including brochures (pp 4-7), an article in the *Spokane Magazine* provides a description of the services offered by the laser skin clinic. (pg 8) On April 25, 2003, Mr. Gelnette was provided with a Letter of Request (pp 9-10) asking for a copy of his business license; names, addresses & telephone numbers of current employees; copies of licenses or certifications; job descriptions; information about the equipment used; access to their appointment book and copies of random selected patient records (Attachment A). This information was provided (pp11-33) by a very cooperative Jeff Gelnette. According to Amy Gelnette, The (IPL) Intense pulse light laser operates with a radio frequency and is used for Tattoo removal, aging spots, sun spots, and hair removal such as bikini lines as well as microdermabrasion for stretch marks. She indicated that a topical anesthetic was applied if the patient was uncomfortable after the procedure. Jeff Gelnette says this practice was discontinued and the only medications applied are the ones the physician uses.

Chyma Miller-Smith of ISU was consulted in regard to a similar investigation she was involved with. Copies of documentation relating to this investigation were provided, also. (Attachment B). Dr. Elizabeth Bianchi was identified as the Medical Director for both Clinics (Seattle & Spokane Valley). Dr. Bianchi was sent a Letter of Cooperation on May 02, 2003. (pp 34-35) Her reply was received on May 21, 2003 (pp 36-43). The investigation was completed and forwarded to the Chief Investigator on May 23, 2003. .

1. Contacts Made	3. Significant Activity
2. Key Evidence / Attachments	4. Prior Case History.

1) Contacts:

Thomas R. Heafey, Health Care Investigator III
Department of Health/Medical Investigations
1500 West Fourth Avenue, Suite 313
Spokane, WA 99204
(509) 458-3642

Jeff Gelnette, Manager
NUVO Laser Skin Clinic
Spokane Valley Mall
14700 E. Indiana, STE 1092
Spokane, WA 99216
(509) 927-9400
FAX: (509) 927-4955
Cell: (509) 869-8828

Chyma Miller- Smith
WA State Dept. of Health
Investigative Service Unit
(360) 236-4659

2) **Key Evidence / Attachments:**

<u>Page</u>	<u>Description</u>
1-3	Letters of Complaint, Notification and Acknowledgement.
4-7	Informational sheets obtained from <i>NUVO</i> of Spokane Valley
8	Article appearing in the <i>Spokane Magazine</i> regarding <i>NUVO</i> .
9-10	Letter of request to Jeff Gelnette, Manager of <i>NUVO</i> .
11-33	Response & requested data from Jeff Gelnette.
34-35	Copy of the Letter of cooperation sent to Dr. Elizabeth Bianchi.
36-43	Dr. Bianchi's response.

ATTACHMENTS:

Attachment A	Randomly selected Patient records from <i>NUVO</i> .
Attachment B	Investigative data obtained from ISU.

3) **Activity:**

<u>Date</u>	<u>Activity</u>
12-10-2002	Complaint received by the WA State Department of Health.
12-10-2002	Initial Assessment Review
12-11-2002	Request for Investigation received MIU/Olympia.
12-11-2002	Investigation assigned to T. Heafey.
12-16-2002	Request for Investigation received MIU/Spokane.
02-24-2003	T/C to Chyma Miller- Smith.
02-26-2003	Reports received from ISU (Attachment B).
02-29-2003	T/C from Chyma Miller-Smith

04-21-2003 T/C to *NUVO*.
04-25-2003 Letter of Request hand-delivered to business.
05-02-2003 Letter of Cooperation sent to Dr. Elizabeth Bianchi.
05-08-2003 T/C from Jeff Gelnette.
05-14-2003 Picked up documentation from Jeff Gelnette.
05-22-2003 Dr. Bianchi's response reviewed.
05-23-2003 Investigation completed and forwarded to the Chief Investigator

4) **Prior Case History:** None

Nuvo *Spokane Valley
Mall*
LASER SKIN CLINICS

JEFFREY A. GELNETTE
MANAGER

14700 E. INDIANA, SUITE 1092
SPOKANE, WA 99216

WWW.NUVOINTERNATIONAL.COM
PHONE: (509) 927-9400 • 1-800-696-0079
FAX: (509) 927-4955

Nuvo *Spokane Valley
Mall*
LASER SKIN CLINICS

DEBRA L. POWELL
TREATMENT SPECIALIST

14700 E. INDIANA, SUITE 1092
SPOKANE, WA 99216

WWW.NUVOINTERNATIONAL.COM
PHONE: (509) 927-9400 • 1-800-696-0079
FAX: (509) 927-4955

Nuvo *Spokane Valley
Mall*
LASER SKIN CLINICS

THERESA S. WYER
TREATMENT SPECIALIST

14700 E. INDIANA, SUITE 1092
SPOKANE, WA 99216

WWW.NUVOINTERNATIONAL.COM
PHONE: (509) 927-9400 • 1-800-696-0079
FAX: (509) 927-4955

nuvo *Spokane Valley
Mall*
LASER SKIN ENHANCEMENT CLINICS



14700 E. INDIANA, SUITE 1092
SPOKANE, WA 99216

WWW.SKINNUVO.COM Nuvointernational.com
PHONE: (509) 927-9400
FAX: (509) 927-4955

DEPARTMENT OF HEALTH
INVESTIGATION SERVICE UNITP.O. BOX 47874
OLYMPIA, WASHINGTON 98504-7874

FAX

Date:

1/24/03

Number of pages including cover sheet:

3

To:

Tom Heafey

Phone:

509-458-3642

Fax phone:

509-458-3638

CC:

From:

CHYMA MILLER-SMITH

Health Professions Quality
Unlicense Practice Program
Investigation Service Unit
P O Box 47874
Olympia, Washington 98504-
7874

Phone:

360.236.4659

Fax phone:

360 586-0123

REMARKS:



Urgent



For your review



Reply ASAP



Please comment

MQAC Laser Policy

ATTENTION: " This message may be confidential. If you received it by mistake, please notify the sender and return the item. All messages to and from the Department of Health may be disclosed to the public."If you have received this message in error, please notify us by telephone immediately, and return the original message to us at the address listed above via U.S. Postal Service. We will, of course, be happy to reimburse you for any costs. Thank you.

10-25-02
MQAC Policy

Use of Lasers in Skin Care and Treatment

Most lasers used for medical or medical like purposes carry an FDA classification that restricts their sale and therefore use to someone with prescriptive authority such as an MD or Dentist. For our purposes here we are addressing only physicians. The Medical Commission holds that the use of a laser for treating or altering skin is the practice of medicine. The Commission however has allowed that the use of a laser for dermatologic purposes, such as hair removal, may be delegated provided a physician provides appropriate oversight.

One may not assume that an MD degree and a valid medical license qualifies a physician to provide appropriate oversight for the dermatologic use of a laser. "Appropriate oversight" here presumes and indeed requires that a physician possess a variety of prerequisite skills:

- 1) The physician must be skilled in the diagnosis, selection and treatment of patients with skin conditions being considered for treatment with a laser.
- 2) The physician must know the indications for and against the various treatments available for the specific skin condition to be treated with a laser and be familiar with the risks, effects and side effects of the proposed laser treatment.
- 3) The physician must be certifiably trained in the theory and use of medical lasers and have sufficient practical hands on experience in the use of a laser to make the oversight of another laser user real and meaningful.

Before delegating the use of a laser to another person the overseeing physician must also assure that that individual as well has both appropriate training in the area of basic dermatology, and demonstrable training and experience in the use of a laser. While this training and experience need not be identical to the physician's, it must be of sufficient similarity and scope to assure that the designee can provide laser based dermatologic services with skill and safety.

Skill in laser based hair removal does not imply skill with other laser cosmetic procedures such as the treatment of congenital and vascular conditions or tattoos. As the complexity of a skin condition increases so does the risk to the patient, and the involvement of a physician in the care of that patient must increase concomitantly. Procedures which carry unusual or significant risks based on age, diagnosis or location on the body should either not be delegated at all or should be delegated only to those individuals whose skills and experience are commensurate with the problem. Such individuals should ideally have a significant background of medical training as a nurse or physician assistant.

Finally the physician must be available to those he or she is overseeing. In this matter availability means that the physician is sufficiently available to the staff to assure appropriate patient selection and treatment. Availability may mean that the physician is in the office proper or in the building, or, it may mean that the physician is available by phone, depending on the facility, the patient, the diagnosis, the person providing the treatment and the nature of the treatment being provided. Again reasonable care and safety, not physician convenience, is the standard.

George Heye, MD
Medical Consultant
Medical Quality Assurance Commission
360-236-4795

(LR 12-18-02)

*** RX REPORT ***

RECEPTION OK

TX/RX NO	6858
CONNECTION TEL	
CONNECTION ID	
ST. TIME	01/27 08:14
USAGE T	01'02
PGS.	3
RESULT	OK

.....

WASHINGTON STATE MEDICAL QUALITY ASSURANCE COMMISSION
REQUEST FOR INVESTIGATIVE SUPPORT

.....

TO: Medical Investigations Unit

FROM: Cindy Hamilton, Intake Coordinator

PHONE #: 236-4805

Spokane
RECEIVED
DEC 16 2002
INVESTIGATIONS

DATE: 12-11-02

CASE #: 02-12-0019MD

RESPONDENT: UNKNOWN

LOCATION: SPOKANE, WA

DATE ASSIGNED: 12-11-02

PRIORITY: 3 CODE: 10

INVESTIGATOR ASSIGNED: THOMAS HEAFY

BACKGROUND COMMENTS

cc confidential

BC

INITIAL ASSESSMENT REVIEW
Case Number: 02-12-0019MD

Date: December 10, 2002
Presented by: Bill N. Crowell, PA-C

Respondent: Medical Unknown Spokane County

Complainant: Confidential

CASE SUMMARY

The Respondent: Is unknown at this time

The Complainant: Confidential

Malpractice Settlement: N/A

The Complaint: Possible aiding or abetting unlicensed practice.

Complaint Review: On December 10, 2002, the MQAC Medical Consultant received a telephone call regarding a hair removal business that was advertising itself as removing hair, treatment of vascular lesions, i.e., leg veins, and superficial skin pigmentation problems. This was accomplished through the use of a pulsed light unit called an "Aurora" and the personnel performing the treatments are reportedly not medically licensed but may have been trained by the company that manufactures the machine. It is alleged that although there may be some medical supervision, there is no physician on site.

Prior Cases:

Code: 04/0

Notification: Yes ✓ No

Investigative Plan:

- Visit location, interview personnel, licensing, etc.
- MD required? If so, Respondent's **statement**.

**DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION - SECTION 5**

INTAKE SHEET

Respondent Information

Case No: 02-12-0019MD Case Opened: 12/10/2002

Name: Unknown Medical, MD Lic/Cert/Reg No: _____ Issued: _____
Address: _____ D.O.B.: _____ Expires: _____

Soc Sec No: _____

School Attended: _____ Year Completed: _____
Specialty: _____ Board Certified: No

Complainant Information

Name: Confidential
Address: _____

Companion Case Information (other Respondent)

Previous Case Information (same respondent)

Case No: <u>01-01-0060MD</u>	Case Disposition: <u>Closed</u>	Reason Closed: <u>Below</u>
Complainant: <u>3 - Identity - Whistlebl...</u>		
Case No: <u>01-05-0014MD</u>	Case Disposition: <u>Closed</u>	Reason Closed: <u>Below</u>
Complainant: <u>DOH Unlicensed Practice Un</u>		
Case No: <u>01-08-0065MD</u>	Case Disposition: <u>Closed</u>	Reason Closed: <u>Below</u>
Complainant: <u>3 - Identity - Whistlebl...</u>		
Case No: <u>01-10-0044MD</u>	Case Disposition: <u>Closed</u>	Reason Closed: <u>NCFA</u>
Complainant: <u>3 - Identity - Whistle...</u>		
Case No: <u>01-12-0015MD</u>	Case Disposition: <u>Closed</u>	Reason Closed: <u>NCFA</u>
Complainant: <u>3 - Identity - Whistleblower Reg...</u>		

***Steps**

A=Assess

RM = Reviewing Member

S=Settlement

I=Investigating

LD=Legal Drafting

LP=Legal Prehearing

LR=Legal Review

LS = Legal Service

RAG=Legal Support

F=Final Action

RPT002

12/10/2002

Page 1 of 3

**DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION - SECTION 5**

INTAKE SHEET

Respondent Information

Case No: 02-12-0019MD

Case Opened: 12/10/2002

Name: Unknown Medical, MD

Lic/Cert/Reg No: _____

Issued: _____

Address: _____

D.O.B.: _____

Expires: _____

Soc Sec No: _____

School Attended: _____

Year Completed: _____

Specialty: _____

Board Certified: No

Case No: 01-12-0050MD

Case Disposition: Closed

Reason Closed: NCFA

Complainant: 3 - Identity - Whi...

Case No: 02-01-0007MD

Case Disposition: Closed

Reason Closed: Below

Complainant: 3 - Identity - Whistleblower Regardi...

Case No: 02-01-0100MD

Case Disposition: Closed

Reason Closed: Below

Complainant: 3 - Identity - Whistleblower ...

Case No: 02-04-0011MD

Case Disposition: Open

Reason Closed: _____

Complainant: 3 - Identity - Whistleblo...

Case No: 02-04-0048MD

Case Disposition: Closed

Reason Closed: NCFA

Complainant: Aging & Adult Services Admi

Case No: 02-04-0062MD

Case Disposition: Closed

Reason Closed: Below

Complainant: 3 - Identity - Whis...

Case No: 02-04-0096MD

Case Disposition: Closed

Reason Closed: NCFA

Complainant: 3 - Identity - Whi...

Case No: 02-06-0030MD

Case Disposition: Closed

Reason Closed: Below

Complainant: 3 - Identity - Whistl...

Case No: 02-10-0006MD

Case Disposition: Open

Reason Closed: _____

Complainant: 3 - Identity - Whistleblower Regardi...

Case No: 02-09-0038MD

Case Disposition: Closed

Reason Closed: No Jurisd

Complainant: 3 - Identity - Whistlebl...

***Steps**

A=Assess
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RPT002

12/10/2002

**DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION - SECTION 5**

INTAKE SHEET

Respondent Information

Case No: 02-12-0019MD Case Opened: 12/10/2002

Name: Unknown Medical, MD Lic/Cert/Reg No: _____ Issued: _____

Address: _____ D.O.B.: _____ Expires: _____

Soc Sec No: _____

School Attended: _____ Year Completed: _____

Specialty: _____ Board Certified: No

Case No: 02-09-0035MD Case Disposition: Closed Reason Closed: Below

Complainant: 3 - Identity - Whistleblower Regarding ...

Case No: 02-09-0037MD Case Disposition: Open Reason Closed: _____

Complainant: Facilities and Services Licen

Case No: 02-11-0039MD Case Disposition: Open Reason Closed: _____

Complainant: 3 - Identity - Whistleb...

***Steps**

A=Assess

RM = Reviewing Member

S=Settlement

I=Investigating

LD=Legal Drafting

LP=Legal Prehearing

LR=Legal Review

LS = Legal Service

RAG=Legal Support

F=Final Action

RPT002

12/10/2002

Page 3 of 3

MEDICAL BOARD
crh0303
INDIVIDUAL NAME
LAST MEDICAL
FIRST UNKNOWN
MIDDLE

ASSESSMENT SYSTEMS, INC.
REAL SYSTEM
(JR,SR,III)

12-10-02
01:05:30 PM
V2.5.74
REFERENCE # UK90000015
SOC SEC NUM - -

RESIDENCE INFORMATION

PHONE: () - COUNTY:
() - LGL ST:

NOTES

+--ADDITIONAL INFORMATION--+	
SEX M =	MARRIED Y =
OTHER NAME	
CORP. OFFICER	=
TRUST ACCOUNT	
BIRTH PLACE	
DATE	- -
SCHOOL CODE	
CE UNITS	0.00 REQD BY - -
+--ADDITIONAL INFORMATION--+	

CURRENT STATUS: U	EXPIRATION DATE: - -	FIRST ISSUE DATE: - -
RENEWAL STATUS:	LAST ACTIVE DATE: - -	LAST RENEWAL DATE: - -
COMPLAINTS O/C: 3/12	AUTHORITY:	

2002-12-0019MD

12-10-2002

22/10

*Aiding and abetting
unlicensed practice*

Complainant

Confidential

*Changed to
Elizabeth J. Bianchi, MD
E 10808 46th
Spokane WA 99206*

CASE NUMBER	COMPLAINANT	COMPLAINT DATE	INVESTIGATOR	TYPE	STATUS
99100068	BOARD OF PHARMACY	10-21-1999		01	CNAX
2000010039	AGING/ADULT SERVICES	01-18-2000		06	CNA2
2000060043	DOH NURSING CMSN	06-15-2000		26	CNAE
2000070063	3 - Identity - Whistleblower Regarding ...	07-25-2000		19	CNAC
2000080080		08-28-2000		25	CNAH
2001010060		01-17-2001		12	CNA2
2001040073	UNLICENSED PRACTICE	04-30-2001		15	CNAE
2001050014		05-03-2001		22	CNA2
2001070029		07-19-2001		01	ASSESS
2001080065		08-24-2001		19	CNA2
2001120015		12-10-2001		19	CNAE
2001120050		12-24-2001		19	CNAM
2002010007		01-03-2002		19	CNA2
2002010012		01-03-2002		31	CNA2
2002010100	3 - Identity - Whistleblower Regarding Healt...	01-31-2002		12	CNA2
2002040011		04-02-2002		19	CNAE

MEDICAL BOARD
crh0303

ASSESSMENT SYSTEMS, INC.
REAL SYSTEM

V2.5.74

12-10-02
01:05:49 PM

CASE NUMBER	COMPLAINANT	COMPLAINT DATE	INVESTIGATOR	TYPE	STATUS
2002040048	AGING AND ADULT SVCS	04-12-2002		19	CNAE
2002040062	3 - Identity - Whistleblower Regarding Healt...	04-15-2002		33	CNA2
2002040085		04-23-2002		19	CNAE
2002040096		04-25-2002		19	CNAE
2002050091		05-31-2002		14	CNAE
2002060030		06-11-2002		19	CNA2
2002090033		09-16-2002		19	CNA1
2002090035		09-23-2002		19	CNA2
2002090037	DOH FACILITIES/SVCS	09-23-2002		19	FDINVT
2002100006	3 - Identity - Whistleblower Regarding Hea...	10-01-2002		19	FDINVT
2002100063		10-18-2002		19	FDINVT
2002110039		11-15-2002		12	ASSESS

2002-12-0019MD

RESPONDENT: Elizabeth Bianchi, MD/*NUVO*

Patient records of:

2 - Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2),...

supplied by
NUVO

ATTACHMENT A

BIANCHI, ELIZABETH A.
02-12-0019MD
(2 OF 2))

2002-12-0019MD

RESPONDENT: Elizabeth Bianchi, MD

**Documentation provided by the
Investigative Service Unit
Relating to an investigation of
Laser Works, Inc. .**

ATTACHMENT B

MEMO TO FILE

December 17, 2002

CASE NO.: 2002-08-0019UI; 2002-09-0004UI

SUBJECT: Dr. John Fisher

On December 17, 2002, an interview was conducted with Dr. John Fisher. He is identified as the Medical Director of Laser Works. Dr. Fisher says he has not been in contact with Eric Moore and has no idea why I would be contacting him.

Dr. Fisher says he became their medical director to help them with financing of the laser, etc. He says he really hasn't had much contact with the business, but receives a monthly check for \$500 from them to use him as the medical director.

Dr. Fisher states in the 3 years he has been involved in the business, he was only called to see someone once, just after the business opened. He has not been to the business in at least 6 months and has not worked with or know any of the employees working at the business.

Dr. Fisher says he is employed full time as the Public Medical Doctor. He works for King County in the jail systems at different locations. Dr. Fisher says it is his understanding Eric Moore and Jeff Schmidt have nurses providing treatment at their office. He was very surprised to hear no medical personnel are working at the office.

Dr. Fisher then explained he a short time ago (month or so) he ordered 4% Lidocaine prescription for the office and it was mailed. He expressed his concern that these complaints were going to affect him and his license to practice.

Dr. Fisher also explained he just finished probation for a complaint with MQAC and the FDA for selling Viagra over the Internet for \$19.99. He doesn't want more problems and said he would cooperate fully in our investigation. Dr. Fisher said he would be preparing a resignation letter to Eric Moore and Laser Works of Seattle. He will fax me a copy. (The resignation letter was received later this same date)

December 20, 2002: On this date, I met with Dr. Fisher. He signed a Witness Notification form and said he will prepare and provide a statement for this investigation. Dr. Fisher was shown the forms obtained from and being used by Laser Works. He became emotional and said he was concerned with the wording used in the forms. He states he never has seen these forms or was involved in the preparation of the forms. He says he had very little to do with the business, but did receive a check monthly.

MEMO TO FILE

December 17, 2002

CASE NO.: 2002-08-0019UI; 2002-09-0004UI

SUBJECT: Eric Moore

On December 17, 2002, an interview was conducted with Eric Moore, owner of Laser Works. Also present at this interview was Jim Voiland, HC Investigator. Mr. Moore states his employees are not performing medical treatment to patients/clients/customers.

Mr. Moore says they did not hire Dr. Fisher to be the Medical Director out of necessity. They hired Dr. Fisher and had him order the lasers as they (he and Jeff (co-owners) could obtain easier better financing on the lasers. Dr. Fisher was mainly a figurehead for the financing, and had little to do with the day-to-day operations of the business. They have not written agreement between Dr. Fisher, Jeff Schmidt, and himself. He says this office has seen 1,000's of people. The employees have been trained by the companies on how to work the lasers. He says nothing the employees do when working with the lasers require a physician or nurse.

Mr. Moore identified one of the respondent's as a cosmetologist (Marilyn Gelnette). He says she started working here June 2002. He explained he is in the process of merging and forming a new company. He identified three employees that perform the laser treatments, etc. They are Sherry Winterstein, Shaney Shoengarth, and Marilyn Gelnette. He says he does not perform the treatments.

Mr. Moore says he or Marilyn Gelnette usually do the intakes on all incoming patients/clients/customers. They find out which areas and describe the process and costs. He says anyone being seen sign a disclosure form as part of the intake process. He used to have an esthetician names Sandra Lee Murillo, but he let her go in July or August 2002 as she wasn't doing her job.

Mr. Moore says as far as Lidocaine being used by the employees, it is only given to someone in pain who requests it. He says it is not a big deal. He can't remember the last time they received any, but says it is very rarely used. He will provide the information. Mr. Moore described how they order it. He faxes a request to Dr. Fisher, who then orders it and it is delivered by mail. When we requested to see where the Lidocaine is kept, Mr. Moore was unable to show any of it to us. He couldn't find it.

The four lasers used here are identified as YAG; QUANTUM IPL; ALEXANDRITE; and SYNERON IPL. All four were viewed and pictures were taken of the treatment rooms, etc. Also, copies of the forms given to patients/clients/customers were obtained at this visit. Mr. Moore states that even though Botox treatments are listed on forms, this office does not perform these treatments. He says they do have a microdermabrasion machine, but do very few treatments.

A review was made of the appointment book and records were obtained. Files were obtained or alleged burned individuals and copied.

Mr. Moore says he will be providing evidence and statements that the three employees are not providing medical treatment or performing any unlicensed practice.

**DEPARTMENT OF HEALTH
INVESTIGATION SERVICE UNIT****P.O. BOX 47874
OLYMPIA, WASHINGTON 98504-7874****FAX**Date: **February 27, 2003**Number of pages including cover sheet: 17**To**

Tom Heafey

Phone: 509-458-3642

Fax phone: 509-458-3638

CC:

From: CHYMA MILLER-SMITHHealth Professions Quality
Investigation Service Unit
P O Box 47874
Olympia, Washington 98504-
7874

Phone: 360.236.4659

Fax phone: 360.586.0123

REMARKS:☐

Urgent

☒

For your review

☐

Reply ASAP

☐

Please comment

RE: Elizabeth Bianchi

ATTENTION: " This message may be confidential. If you received it by mistake, please notify the sender and return the item. All messages to and from the Department of Health may be disclosed to the public."If you have received this message in error, please notify us by telephone immediately, and return the original message to us at the address listed above via U.S. Postal Service. We will, of course, be happy to reimburse you for any costs. Thank you.

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1424 FOURTH AVENUE, SUITE 909
SEATTLE, WASHINGTON 98101-2217
VOICE: (206) 903-0664
FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

DATE: FEBRUARY 26, 2003
TIME: 3:33 PM
NUMBER OF PAGES WITH COVER: 7

FACSIMILE COVER SHEET

TO: Chyma Miller-Smith
Unlicensed Practice Program
DOH

FAX NO.: (360) 586-0123
TELE. NO: (360) 236-4659

FROM: Stephan O. Fjelstad

RE: DOH Investigation of Laser Works of Seattle—Letter

CLIENT REF.:

If any of these pages are not legible or you do not receive all the pages, please call (206) 903-0664.

COMMENTS:

CONFIDENTIALITY NOTICE: This facsimile transmission may contain confidential and privileged information. The information is intended for the use of the addressee only. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of this telecopied information is strictly prohibited. If you have received this telecopy in error, please immediately notify us by telephone to arrange for a return of the original message to us.

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1424 FOURTH AVENUE, SUITE 909
SEATTLE, WASHINGTON 98101-2217
VOICE: (206) 903-0664
FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

February 26, 2003

Chyma Miller-Smith
Health Care Investigator
Unlicensed Practice Program
Department of Health
PO Box 47874
Olympia, WA 98504-7874

Re: Investigation of Laser Works of Seattle Employees by Department of Health

Dear Ms. Miller-Smith:

As you know, I represent the three employees of the company Laser Works of Seattle, namely Marilyn Gelnette, Shancy Shoengarth and Cheri Winterstein (collectively, the "employees") regarding the Department of Health (DOH) investigation as to whether these individuals have practiced medicine. My understanding is that your program is now coordinating the investigation for DOH.

I previously wrote a letter dated January 15, 2003, to Gayle M. Crowley, the initial Health Care Investigator assigned to this case, explaining our preliminary position on the issue of whether we believe the employees have practiced medicine. I presume that letter is part of the file Ms. Crowley forwarded to your office and it gives a detailed background of the nature of Laser Works and the work its employees perform. (If for any reason my letter to Ms. Crowley has not reached you or is not part of the file, please let me know and I will supply another copy immediately.) Our position in the letter to Ms. Crowley is that we do not believe the employees have practiced medicine. Regardless of how that question may ultimately be resolved, however I wish to emphasize on behalf of my clients that our singular aim is to ensure that they and Laser Works are in compliance with the provisions set forth in the recent Medical Quality Assurance Commission (MQAC) 10-25-02 policy statement entitled "Use of Lasers in Skin Care and Treatment" (the Policy). I write to you now to explain additional actions that have been taken to ensure compliance, to provide additional information not contained in my previous letter to Ms. Crowley and to seek your guidance in achieving satisfactory compliance if additional measures are needed.

February 26, 2003
Page 2

As you know, the Policy allows the use of a laser for dermatologic purposes, such as hair removal, to be delegated with appropriate oversight by a physician. The Policy discusses the scope of "appropriate oversight" and lists three prerequisite skills the physician should possess:

- 1) The physician must be skilled in the diagnosis, selection and treatment of patients with skin conditions being considered for treatment with a laser.
- 2) The physician must know the indications for and against the various treatments available for the specific skin condition to be treated with a laser and be familiar with the risks, effects and side effects of the proposed laser treatment.
- 3) The physician must be certifiably trained in the theory and use of medical lasers and have sufficient practical hands on experience in the use of a laser to make the oversight of another laser user real and meaningful.

Until very recently, Laser Works had retained Dr. John Fisher as its medical director to provide physician oversight and be available to consult with the employees or to assist Laser Work's customers should any physical problems arise. Dr. Fisher unfortunately resigned late last December 2002 as medical director. His resignation was one of the primary concerns Ms. Crowley emphasized to me in a meeting we held on January 15, 2003 to discuss the DOH investigation.

Following Dr. Fisher's resignation, Laser Works had immediately sought the assistance of a new medical director, and on the same day as the meeting with Ms. Crowley, January 15, 2003, Dr. Elizabeth Bianchi agreed to act as Laser Work's new medical director effective immediately. Dr. Bianchi contacted Dr. George Heye of MQAC within a few days of her appointment as Laser Works' new medical director to discuss the Policy and his insights on the requirements for compliance. Dr. Bianchi is committed to working with the DOH and MQAC as closely as possible to satisfy any concerns raised in the investigation.

After her appointment as medical director, Dr. Bianchi quickly got up to speed on the procedures followed by the Laser Works employees and the equipment they use through telephone calls and spent extensive time visiting the office to meet personally with the employees and review procedures and treatments followed. She concluded based on her personal observations that the employees are well experienced and competent in performing the services and treatments offered at Laser Works. At this time, it is anticipated that Dr. Bianchi will make regular personal visits to Laser Works' office at least twice monthly and has been and will remain available by telephone (including cell phone) to the employees should any special need arise at any time.

We believe Dr. Bianchi's credentials and experience more than satisfy the various physician skill and oversight guidelines prescribed in the Policy. She has been board certified in family practice since 1998 and is generally qualified concerning the various skin condition

February 26, 2003

Page 3

analyses and skills set forth in points 1) and 2) quoted above from the Policy. More specifically, Dr. Bianchi has served as the medical director for another cosmetic laser hair removal and skin rejuvenation center, Skin Nuvo of Spokane, since October 2002. This center offers most of the same services as those provided by the Laser Works employees. It also utilizes very similar laser or pulsed light equipment to that used by the Laser Works employees. In short, this prior experience and familiarity with procedures, equipment and typical customer skin concerns (including potential risks and effects) of a cosmetic laser hair removal and skin care center give Dr. Bianchi an ideal background to provide physician oversight for Laser Works.

Dr. Bianchi has also received and continues receive specialized training and certification in cosmetic medicine, laser hair removal and other skin rejuvenation treatments. Last year she successfully completed an advanced certification course in California for *FotoFacial* and multi-application of pulsed optical light and radio frequency technology. This course was provided by Stephan Mulholland, MD and Patrick Bitters, MD, who are widely known and published in as specialists in the area of cosmetic laser, intense pulsed light and pulsed light/radio frequency treatments (credit for the course applied toward the Physician's Recognition Award of the American Medical Association).¹ Dr. Bianchi's training related to cosmetic medicine includes her certification for intensive hands-on Botox injection training through the Perfect Skin Laser Center with Dr. Ivyl W. Wells in Boise, Idaho. She is also registered for an intensive two-day Aesthetics Workshop in approximately two weeks (March 2003) that includes advanced training in hair removal, the role of lasers in aesthetics, skin resurfacing, micro-dermabrasion, Botox, collagen injection and other procedures. (We would be happy to provide you copies of certification and coursework documentation of Dr. Bianchi's training, as well as her resume, should you request it.)

We believe Dr. Bianchi's cumulative experience, specialized training and credentials make her exceptionally qualified to provide the employees of Laser Works with physician oversight and to act as Laser Works' medical director. We are also confident that her location in Spokane will not impede her ability to handle any issues that may arise. As mentioned above, she will schedule regular visits to Laser Works' office, will be always accessible for consultation by telephone and, if special trips are ever necessary, has ready access by airline shuttles that leave for Seattle every one-and-one-half hours.

Laser Works has also always had available for consultation a registered nurse, Bonnie J. Schmidt. Ms. Schmidt has been a registered nurse since 1978 and is currently licensed in Washington, California, Oregon, Nevada, Arizona and New York. She currently acts as a medical laser consultant to various medical doctors and laser clinics throughout Washington, Oregon, California and Nevada.

¹ It bears mention that two of the four machines used by the Laser Works employees are intense pulsed light and pulsed light/radio frequency devices rather than lasers.

February 26, 2003

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Ms. Schmidt's experience with laser technology is extensive. She was first certified as a laser technician in 1998. She assisted in pioneering the Alexanderite laser for ESC Medical Systems in 1998 and established starting parameters and protocols for ESC training manuals. She also assisted in pioneering the 1094 YAG laser and established starting parameters and protocols for Altus Medical laser training manuals. Ms. Schmidt is also certified in the use of intense pulse light systems manufactured by Syneron (the Aurora) and Lumines Medical Systems (the Quantum) for hair removal and Photo rejuvenation. She also obtained certification from Dr. Patrick Bitters (mentioned above regarding Dr. Bianchi's training); from Altus Medical for the 1064 YAG laser for treatment of veins and advance training in hair removal for dark skin types 3, 4 and 5; and from Biomedic for Obagi. She also has advanced training in micro-dermabrasion. Ms. Schmidt has personally performed over 4000 laser treatments with various lasers and intense pulse light systems for hair removal, photo facial, vein treatment, sun damage and age spot treatments.

Although she is not located in Washington, Ms. Schmidt has occasionally visited the Laser Works office in Seattle and has always been a resource available by telephone. Laser Works has now determined that she will increase the time she spends at Laser Works and be on site at the Laser Works office one day each week. She will also continue to be available at all times by telephone should any need arise.

In my letter to Ms. Crowley, I describe in detail the background of the employees in the various procedures they perform at Laser Works (*see* pages 2-3). Suffice here to say that each of them is well experienced, skilled and competent, as Dr. Bianchi agrees. We are confident that they compare favorably with other persons who provide the same services in this industry.

The consistent lack of harm or injury to Laser Works customers over the years is perhaps the best testament to the employees' high level of professional competence as a group. Now in its fourth year of operation, Laser Works has not once received a complaint evidencing any type of serious or permanent injury caused to a Laser Works customer by any of the employees during their tenures at the company. Laser Works' owners estimate that the company treats approximately three to five hundred customers each month; roughly four to five thousand yearly. Despite these numbers, customer complaints of any type are extraordinarily rare. As is explained to customers prior to treatment, some redness, puffing of the skin and other minor irritations sometimes follow treatment, conditions that are transient and strictly temporary. To the knowledge of Laser Works' management and employees, there has not been a single incident of serious or permanent burning, scarring or skin disfigurement caused by Laser Works' during its entire existence.

When Ms. Crowley of the DOH initially visited Laser Works, she collected charts on several of Laser Works' customers. We assumed these charts might have somehow been related to a communication or complaint to DOH that triggered the investigation. Laser Works contacted the persons whose charts Ms. Crowley had taken. Not one of them indicated

February 26, 2003

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dissatisfaction with treatment by the employees of Laser Works. In fact, not one of them contacted said they had complained in any fashion about Laser Works' treatments. To the contrary, these customers complimented Laser Works' services, indicated they would use its services again, and even volunteered to attest to this satisfaction in writing. We would very much like to know the nature of whatever contact or communication triggered the current DOH investigation, as the details of such communication have not been shared with us. If some customer of Laser Works has indeed been injured, Laser Works would certainly like to hear this and take whatever measures are necessary or that you would recommend to avoid this happening again. Until we learn otherwise, Laser Works remains unaware of a single incidence in which its employees have caused customer harm.

On a different topic, we would also like to address the question of whether the laser and pulse light systems used at Laser Works are equipment that can only be sold to persons with prescriptive authority such as medical doctors. Again, this subject is dealt with in the letter to Ms. Crowley in detail, but since the time that letter was written we have continued to look into this issue and would appreciate information and guidance from you.

The Policy indicates that the MQAC regards most lasers used for medical or medical like purposes as restricted for sale to medical personnel with prescriptive authority. Whether the particular machines used by Laser Works (identified in the letter to Ms. Crowley, p. 3) can only be purchased by such persons under FDA regulations, and whether the particular manufacturers of the systems do so restrict their sale, remain issues that may or may not have an impact on the DOH investigation of Laser Works, but which in any event we would like to better understand. None of the manufacturers of the four machines Laser Works uses informed Laser Works that the systems could only be purchased by a physician with prescriptive authority because of FDA state or any other regulatory or other constraints. Two of them insisted that a doctor be on the leases as a matter of financial security. As a result, Laser Works purchased two of its systems with Dr. Fisher's name and assistance, and two of them without his name or any involvement by Dr. Fisher or by anyone with prescriptive authority.

Specifically, Lumines Medical Systems is one of the companies that have made its lasers available for purchase to the owners of Laser Works without any restriction or even inquiry about persons with prescriptive rights. No such restriction was mentioned in the documents that accompany the equipment. The Lumines lasers have been made available *via* personal payment and/or financing through conventional banks or other means with no involvement of a physician whatsoever. Nonetheless, when I met with Ms. Crowley, she asserted the view that the various manufacturers, including Lumines, can only sell their systems to persons with prescriptive authority.

The point is simply that Laser Works and its employees were never aware that its laser and intense pulse light systems might have been subject to such restrictions. Particularly if this is true and may have some impact on the employees, and also for purposes of Laser Works'

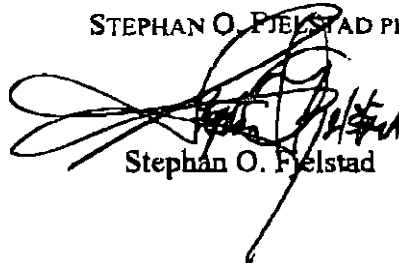
February 26, 2003
Page 6

current and future dealings with industry laser or IPL manufacturers, we would very much appreciate information and direction from you on this matter.

Please contact me at your earliest convenience in response to this letter. On behalf of the employees, it is our continuing commitment to cooperate with all involved in this investigation and to initiate any changes the DOH believes are necessary. Dr. Bianchi also makes this a priority matter and is available to you at any time.

Very truly yours,

STEPHAN O. FJELSTAD PLLC



Stephan O. Fjeldstad

SOF:sof
cc: clients

*** RX REPORT ***

RECEPTION OK

TX/RX NO	6916
CONNECTION TEL	
CONNECTION ID	
ST. TIME	02/27 10:39
USAGE T	05'57
PGS.	18
RESULT	OK

**DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION**

**CONFIDENTIAL INVESTIGATION REPORT
PREPARED FOR THE
SECRETARY, DEPARTMENT OF HEALTH**

Case # 2002-09-0004UI

RESPONDENT: MARILYN GELNETTE

(Companion Case #2002-08-0019UI Winterstein & #2002-12-0013UI Shoengarth)

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APPENDIX F - POSSIBLE VIOLATIONS

APPENDIX G - ACTIVITY REPORT

APPENDIX H - REQUEST FOR INVESTIGATION

Investigator: Gayle M. Crowley
Health Care Investigator

APPROVED BY _____ DATE _____

APPENDIX A

RESPONDENT INFORMATION

NAME: MARILYN GELNETTE

BUSINESS ADDRESS: 411 Strander Blvd., Suite 108
Tukwila, WA 98188

BUSINESS TELEPHONE #: (206) 575-8300

RESIDENCE ADDRESS: N/A

RESIDENCE TELEPHONE #: N/A

LICENSE NUMBER: Unlicensed

DATE ISSUED: N/A

EXPIRATION DATE: N/A

BIRTH DATE: N/A

SPECIALIZATION: N/A

PREVIOUS COMPLAINT HISTORY: 0/0

ATTORNEY IDENTIFICATION: Stephan O. Fjelstad, PLLC

APPENDIX B

COMPLAINANT INFORMATION

NAME:

BUSINESS ADDRESS:

BUSINESS TELEPHONE # :

RESIDENCE ADDRESS: N/A

RESIDENCE TELEPHONE # : N/A

ATTORNEY: N/A

ATTORNEY ADDRESS: N/A

ATTORNEY TELEPHONE # : N/A

APPENDIX C
CONTACT LIST

John A. Fisher, MD
33C Etruria Street
Seattle, WA 98109
(206) 680-7752 Home
(206) 205-2410 Work
(206) 680-7752 Pager

Eric Moore
Laser Works of Seattle
411 Strander Blvd., Suite 108
Tukwila, WA 98188
(206) 575-8300
(206) 501-7710 Cell

George Heye, MD
Medical Consultant
Medical QA Commission
1300 SE Quince
P. O. Box 47874
Olympia, WA 98504
(360) 236-4795

Kathy Maynor
Altus Medical, Inc.
821 Cowan Road
Burlingame, CA 94010
((650) 259-5586

Rosie McGrew
Department of Licensing
Cosmetology
(360) 664-6625

Elizabeth Bianchi, MD
10808 46th Ave.
Spokane, WA
(509) 926-8462 Home
(509) 995-0368 Cell

Gayle M. Crowley
Health Care Investigator
20435 72nd Ave., S, Suite 200
Kent, WA 98032
(253) 395-6709

APPENDIX D

GENERAL SUMMARY

THE INFORMATION CONTAINED IN THIS REPORT, WITH IT'S ACCOMPANYING EVIDENCE AND EXHIBITS, SHOULD BE CONSIDERED IN CONJUNCTION WITH THAT INFORMATION INCLUDED IN THE COMPANION CASE FILES FOR THE MATTER REFERENCED ABOVE ON THE COVER PAGE OF THIS REPORT.

This investigation was initiated by receipt of a complaint at the Unlicensed Program of the Department of Health, from Jason Kagihara, on September 4, 2002. 3 - Identity - Whistleblower..., complainant, says he received treatment for hair removal from the respondent on August 28, 2002. He alleges the respondent, Marilyn Gelnette, told him she could guarantee him 100% that if he had treatment on his cheek, he would be able to go to work and be fine. He says he let her perform the treatment. He alleges she only treated his left cheek because the laser broke before she could finish the other side. He alleges after the treatment, his cheek was red and he received blisters. At the date of this E-mail complaint, September 4, 2002, he alleges his cheek is starting to get back to their normal color.

The complainant is wondering what can be done to stop this from happening to him or another person. He says no one should go through this treatment. **Page 1**

On September 9, 2002, the Unlicensed Program requested a field investigation be conducted to verify if the respondent is providing any type of medical services for which requires licensure. **Page 2**

On September 17, 2002, a telephone interview was conducted with the complainant of the companion case file. She provided names of patients and also gave information regarding Laser Works and how the business is run.

On October 22, 2002, information was obtained from the Internet website for the State of Washington Cosmetology Board, including the requirements for licensure. **Pages 3-12**

On December 17, 2002, information about laser treatment and equipment from various agencies was obtained from the Department of Health, Unlicensed Program Manager. **Pages 13-30**

On December 17, 2002, a telephone interview was conducted with Dr. John Fisher, medical director of Laser Works, Inc. Dr. Fisher was not aware an investigation was open. He became the medical director to help the company with financing of the laser. He doesn't have much contact with the business, but does receive a monthly check for \$500 for them to use him as their medical director.

Dr. Fisher states in the three years he has been involved in the business, he was only called to see someone once, just after the business opened. He has not been to the business in at least six months and has not worked with or know any of the employees working at the Laser Works.

Dr. Fisher is full time employed as the Public Medical Doctor for King County, in the jail systems at different locations. It is his understanding the owners of Laser Works, Inc. have nurses

providing treatment in their offices. He is unaware of any non-medical personnel providing treatment to patients.

Dr. Fisher explained he ordered Lidocaine (later identified as 5% topical) for the business and the prescriptions were mailed directly to Laser Works. A Memo To File was prepared from this interview. **Page 31**

On December 17, 2002, a field visit was made to the respondent's place of employment, Laser Works, Inc., with health care investigator Jim Voiland. Pictures were taken of the front reception office, treatment rooms, equipment being used for treatment, and framed posters.

An interview was conducted with owner Eric Moore. Mr. Moore states his employees are not performing any medical treatment to individuals who come in for their services. He identified these individuals as clients or customers.

Mr. Moore says they did not hire Dr. Fisher to be the medical director out of necessity. They hired Dr. Fisher so they could have him order the lasers and obtain easier and better financing. Dr. Fisher was mainly a figurehead for the financing, and had little to do with the day-to-day operations of the business.

Mr. Moore says this office has seen 1,000's of people. The employees have been trained by the companies on how to work the lasers. He says nothing the employees do when working with the lasers require a physician or nurse. He identified the respondent as being a cosmetologist and that she started working her in June 2002. He and the respondent usually do the intakes on all incoming patients/clients/customers. They find out which areas and describe the process and costs.

When Mr. Moore was asked about the respondent and companion case respondents using prescription strength Lidocaine on patients/clients/customers, he says Lidocaine is only given to someone in pain that requests it. He says it's not a big deal. He couldn't remember the last time they received any Lidocaine, but says it is rarely used. He faxes a request to Dr. Fisher, who then orders it and it is delivered by mail to the business. Mr. Moore was unable to show us a container of Lidocaine or where it is stored in the office, when asked, but walked around the office and opened cabinet doors.

Mr. Moore described the four lasers being used. He says they do have a microdermabrasion machine, but do very few treatments. Even though botox treatments are listed on Laser Works forms, he says this office does not perform these treatments. A Memo to File was prepared from this interview.

A copy of all Laser Works forms and brochures, located in the front reception office, were obtained. A review of these forms included the following:

- *Reminder and Referrals* – This form includes the following comment: "Following a botox treatment you should see improvements within 72 hours..."
- *Informed Consent Form* – Per owner Eric Moore, this is the new form they are using. This form first sentence reads, "I understand that I will receive medical treatment From Laser Works of Seattle."
- *Patient Medical History*

- Patient Medical History – Vascular Treatment
- Post Treatment – Vascular
- Pre-Treatment – Vascular
- Treatment Log
- Medical History – Skin Rejuvenation
- Informed Consent – Microdermabrasion
- Informed Consent – Skin Rejuvenation
- Client Information Skin Rejuvenation
- Skin Rejuvenation (IPL) Post Treatment Care

A review was made of Laser Works appointment book. A sample of files were obtained, including individuals previously identified by the complainant and companion case file complainant. **Pages 32-134**

On December 17, 2002, a letter was delivered to the respondent and an interview was conducted. The respondent denied she is performing any type of medical treatment or practicing medicine. The respondent did not want to sign the Licensing Requirement Notification at this time. **Pages 135-137**

On December 17, 2002, Dr. Fisher faxed a copy of his resignation as Medical Director for Laser Works, Inc. A telephone message for Dr. Fisher verified this letter was also faxed to Eric Moore at his home, per Mr. Moore's request. **Page 138**

On December 18, 2002, a copy of the Medical Quality Assurance Commission's Policy was obtained from Dr. Heye. **Pages 139-140**

On December 19, 2002, information regarding the drug, 5% Xylocaine (Lidocaine) was obtained from the 1997 Edition of the Physicians' Desk Reference. **Page 141**

On December 19, 2002, information was obtained from several Internet Websites, including the Federal Drug Administration (FDA), and copies printed. Further contact was made with Kathy Maynor at Altus Medical. Ms. Maynor faxed laser FDA information. She also provided the explanations showing how the lasers are categorized, who can buy them, and who can use them. **Pages 142-184**

On December 20, 2002, an interview was conducted with Dr. John Fisher. Dr. Fisher provided documents he had pertaining to his association and agreements with owners Eric Moore and Jeff Schmidt of Laser Works. These documents include copies of laser lease agreements.

During this interview, Dr. Fisher signed a Witness Notification Form. He expressed his concern about the investigation and how it could affect his license to practice. **Pages 185-204**

On December 23, 2002, a Notice of Appearance was received from the respondent's attorney, Stephan Fjelstad. Mr. Fjelstad is also representing the two companion case file respondents.
Page 205

During the course of conducting this investigation, Dr. Fisher provided correspondence by E-mail. Dr. Fisher also faxed a copy of the termination of the laser leasing agreement between himself, Jeff Schmidt, and Eric Moore. **Pages 206-214**

On January 15, 2003, Dr. Fisher provided a statement. He described in detail how he became the medical director of Laser Works, Inc. Dr. Fisher said he was paid primarily to compensate him for the risk of putting his name on the lease of the ESC Alexandrite laser.

Dr. Fisher says he was never involved in the planning or set up of the clinic or the day-to-day running of the clinic. It was his understanding the laser work was to be done by RN's. In the several years he has been the medical director, Dr. Fisher says he has been called only once, during the first year of operation.

Dr. Fisher also discusses his ordering of the prescription for Lazercaine, a topical anesthetic of 5% lidocaine. **Pages 215-216**

On January 15, 2003, the respondent's attorney provided the respondent's written response. This written response is the same one as for the two companion case file respondents. The respondent's attorney describes in detail how Laser Works, Inc. is performing its operations at the Tukwila location. He says prior to the business opening it's door, the principals diligently explored statutory licensing and regulations in Washington.

The respondent's attorney describes treatment provided by employees at Laser Works and says the nature of their services is strictly cosmetic. He says none of the employees diagnose or offer advice related to health problems. Customers simply want to enhance their appearance.

The respondent's attorney says the respondent has worked with laser and pulsed light technology for over two and one half years and also does microdermabrasion at Laser Works. He says she holds a license in electrolysis and cosmetology in California, where she lived formerly.

The respondent's attorney states none of the employees, including the respondent, have ever prescribed or dispensed any drug or medicine for internal use to any customer. He denies any employees have stored or supplied any lidocaine at the premises, and have no intention of acquiring more for any purpose. He says the last time Laser Works received lidocaine was several months ago when a small shipment of fifteen containers were ordered. The respondent's attorney says the lidocaine was supplied to a tiny fraction of Laser Works customers to be applied to their skin prior to treatments.

The respondent's attorney explains Dr. Fisher's role as medical director for Laser Works, Inc. He says Dr. Fisher has never, to their knowledge, prescribed drugs or medicines to any customers.

The respondent's attorney denies the services Laser Works and their employees are providing qualify as the practice of medicine under Washington State law.

The respondent completed the Licensing Requirement Notification form by signing and also providing a written statement. **Pages 217-229**

On January 27, 2003, patient treatment records were obtained by subpoena. These were a sampling of records for individuals receiving treatment from December 17, 2002 through January 15, 2003.

A review of the records indicates several patients/clients/customers were given lazercaine (lidocaine) during the treatment process. This is noted on Evidence Page #411, and Evidence Page #621. A comment from the treatment provider suggesting lidocaine is listed on Evidence Page #455. **Pages 230-683**

On January 27, 2003, the respondent's attorney provided copies of three forms that have been revised and are being used at Laser Works. They are as follows:

- Customer Comments and Concerns
- Informed Consent Form
- Client Medical History

Pages 684-687

On January 31, 2003, a telephone interview was conducted with Dr. Elizabeth Bianchi. She states she is currently the medical director for Laser Works Inc. Dr. Bianchi states she is also the medical director of Nouveau (sp?) of Spokane. She says she lives and works in Spokane, but has made a visit to Laser Works. She also works for Planned Parenthood in Spokane. Dr. Bianchi said she understands she is responsible for the day to day treatment being provided at Laser Works, and is going to work with the Medical Quality Assurance Commission.

On February 18, 2003, a telephone interview was conducted with the complainant. The complainant says it took almost two weeks for his cheek to look normal again after receiving treatment from the respondent. He alleges the treatment was stopped because the laser broke before the respondent could finish. He was given a white antibiotic cream to put on his cheek by the respondent.

APPENDIX E

EVIDENCE & ATTACHMENTS

<u>Page #'s</u>	<u>Description</u>
1	Respondent's E-mail complaint letter received September 4, 2002.
2	Request for field investigation by Unlicensed Program Manager.
3-12	Information obtained from the Cosmetology Board.
13-30	Faxed information and documents received from the Unlicensed Program Manager.
31	Memo to File of telephone interview with Dr. Fisher.
32-33	Memo to File of interview with Eric Moore.
34-42	Digital pictures taken at Laser Works Inc.
43	Picture disk.
44-61	Laser Works forms.
62-63	Laser Works brochures.
64—69	Treatment records of 2 - Healthcare Informatio...
70-79	Treatment records of 2 - Healthcare Informat...
80-93	Treatment records of 2 - Healthcare Information Readily L...
94-102	Treatment records of 2 - Healthcare Informatio...
103-109	Treatment records of 2 - Healthcare Information R...
110-120	Treatment records of 2 - Healthcare Information ...
121-129	Treatment records of 2 - Healthcare Information Readily...
130-134	Treatment records of 2 - Healthcare Informatio...
135-137	Unlicensed letter delivered to respondent.
138	Faxed copy of Dr. Fisher's resignation letter to Eric Moore and Laser Works, Inc.
139-140	Medical Quality Assurance Commission's Policy on Use of Lasers in Skin Care and Treatment.
141	Physician's Desk Reference (1997 edition) of drug 5% Xylocaine (lidocaine).

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142-148 Laser information obtained from various Internet websites.

149-157 Laser Facts information obtained from FDA Internet website.

158-184 Faxed information and E-mail received from Kathy Maynor, Altus Medical.

185 ASI printout of Dr. John Fisher's license information.

186-203 Records and documents obtained from Dr. Fisher.

204 Witness Notification form of Dr. Fisher.

205 Notice of Appearance from the respondent's attorney, Stephan Fjelstad.

206 Termination of the 11/19/1999 Laser leasing agreement received from Dr. Fisher, dated December 23, 2002.

207-214 E-mail correspondent with Dr. Fisher.

215-216 Statement of Dr. Fisher.

217-225 Respondent's written response signed and submitted by respondent's attorney.

226 Licensing Requirement Notification form signed by the respondent.

227-229 Correspondence from the respondent's attorney.

230-262 Daily appointment book records of Laser Works, Inc.

263-269 Treatment records of 2 - Health...

270-274 Treatment records of 2 - Healthcare Informati...

275-283 Treatment records of 2 - Healthcare Infor...

284-293 Treatment records of 2 - Healthcare Informati...

294-297 Treatment records of 2 - Healthcare Informati...

298-310 Treatment records of 2 - Health...

311-313 Treatment records of 2 - Healthcare Informati...

314-317 Treatment records of 2 - Healthcare Informati...

318-324 Treatment records of 2 - Healthcare Infor...

325-329 Treatment records of 2 - Healthcare Information Re...

330-337 Treatment records of 2 - Healthcare Informatio...

338-349 Treatment records of 2 - Healthcare Information R...

350-358 Treatment records of 2 - Healthcare Informatio...

359-369 Treatment records of 2 - Healthcare Infor...

370-385 Treatment records of 2 - Healthcare Informat...

386-396 Treatment records of 2 - Healthcare Information Rea...

397-409 Treatment records of 2 - Healthcare Information R...

410-418 Treatment records of 2 - Healthcare Information...

419-421 Treatment records of 2 - Healthcare I...

422-427 Treatment records of 2 - Healthcare Informati...

428-431 Treatment records of 2 - Healthcare Infor...

432-452 Treatment records of 2 - Healthcare Information...

453-459 Treatment records of 2 - Healthcare Information...

460-469 Treatment records of 2 - Healthcare ...

470-474 Treatment records of 2 - Healthcare Informati...

475-479 Treatment records of 2 - Healthcare Infor...

480-484 Treatment records of 2 - Healthcare Informatio...

485-489 Treatment records of 2 - Healthcare Informat...

490-493 Treatment records of 2 - Healthcare Infor...

494-499 Treatment records of 2 - Healthcare Informatio...

500-507 Treatment records of 2 - Healthcare Information Readily...

508-511 Treatment records of 2 - Healthcare Information ...

512-524 Treatment records of 2 - Healthcare Informa...

525-534 Treatment records of 2 - Healthcare Informati...

535-543 Treatment records of 2 - Healthcare Informati...

544-547 Treatment records of 2 - Healthcare Inf...

548-556 Treatment records of 2 - Healthcare Inf...

557-560 Treatment records of 2 - Healthcare Informati...

561-565 Treatment records of 2 - Healthcare Infor...

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566-580 Treatment records of 2 - Healthcare Informa...
581-583 Treatment records of 2 - Healthcare Inform...
584-594 Treatment records of 2 - Healthcare Inf...
595-597 Treatment records of 2 - Healthcare Informa...
598-612 Treatment records of 2 - Healthcare Informati...
613-618 Treatment records of 2 - Healthcare Inform...
619-626 Treatment records of 2 - Healthcare Inform...
627-635 Treatment records of 2 - Healthcare Information Read...
636-644 Treatment records of 2 - Healthcare Informati...
645-652 Treatment records of 2 - Healthcare I...
653-665 Treatment records of 2 - Healthcare Information Rea...
666-668 Treatment records of 2 - Healthcare Infor...
669-673 Treatment records of 2 - Healthcare I...
674-677 Treatment records of 2 - Healthcare Informat...
678-680 Treatment records of 2 - Healthcare Informati...
681 Subpoena served requesting appointment schedules and patient treatment records.
682-683 Letter from respondent's attorney regarding the subpoena request and records.
684-687 Revised forms of Laser Works, Inc.

APPENDIX F
POSSIBLE VIOLATIONS

RCW 18.130.190

APPENDIX G
ACTIVITY REPORT

1. 09-16-2002 Received case file.
2. 09-16-2002 Reviewed case file. Field visit will be necessary. This case is companion to #0019 unlicensed case. Different respondents, but same business office.
3. 09-17-2002 Reviewed case and discussed with Lloyd and Jim.
4. 09-17-2002 Researched information.
5. 09-17-2002 T/C to C on companion case file. Conducted interview with C over the telephone. C does not want to sign a Whistleblower. She was actually an employee of the business. She gave information regarding the business and how it is run. Former employee.
6. 09-17-2002 Looked up on the Internet and other information on ASI and also telephone book.
7. 09-17-2002 T/C to business. Obtained business hours, etc.
8. 10-22-2002 T/C to Chyma. ?'s concerning what an unlicensed can do regarding Laser, Chemical Peels, etc. She has had a case before, but not the same as these.
9. 10-22-2002 Looked up on the Internet information about the Cosmetology Board, etc. Printed the information.
10. 10-22-2002 T/C to the Cosmetology Board. Left message for contact with someone here.
11. 10-22-2002 T/C from Rosie, Cosmetology Board.
12. 12-16-2002 Prepared unlicensed letter to deliver to R at unannounced field visit to Laser Works.
13. 12-17-2002 T/C to Chyma, unlicensed Program Manager. She will fax information to me on laser equipment and use, etc.
14. 12-17-2002 Received faxed information. Reviewed fax.
15. 12-17-2002 T/C to Jim Voiland, regarding meeting me this AM at Laser Works.
16. 12-17-2002 T/C to Dr. Heye, MQAC consultant. Discussed case, etc., and what information the MQAC has regarding any policy with lasers and who can

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provide laser treatment. Made arrangements to obtain this information from him when I come down to Olympia on December 18, 2002.

17. 12-17-2002 T/C to the Medical Director, Dr. Fisher. Left a message for him to contact me.
18. 12-17-2002 T/C from Dr. Fisher. Conducted a partial telephone interview with Dr. Fisher regarding his role and part with Laser Works. Dr. Fisher is going to fax me a copy of the resignation he is sending to Laser Works and Eric Moore. Made arrangements to meet with Dr. Fisher on 12/20 at 6:15 AM.
19. 12-17-2002 Met up with Jim and conducted an unannounced F/V to Laser Works.
20. 12-17-2002 Met with Eric Moore and discussed information, etc. Viewed the offices and equipment and took pictures of the equipment.
21. 12-17-2002 Obtained evidence and documents from office. Obtained patient files from office to copy and return to the office.
22. 12-17-2002 Made copies back at the Kent office and returned the files to Laser Works. When I returned, Eric Moore had more ?'s.
23. 12-17-2002 Met with R and delivered unlicensed letter. Discussed case, etc.
24. 12-18-2002 Met with MQAC medical consultant, Dr. Heye and obtained copy of *MQAC Policies of the use of Laser*. Also met with MQAC Chief Investigator Jim Smith, discussed company's medical director and his part in the company, etc.
25. 12-18-2002 Reviewed MQAC Policy on the Use of Lasers in Skin Care and Treatment, dated October 25, 2002. Made notes of ?'s to ask Dr. Heye.
26. 12-19-2002 T/C to Chyma. ?'s after reviewing guidelines. Can I give Eric Moore a copy of this, etc. Per Chyma, yes, but to clear with Medical. Also, they are in process of opening complaint on other unlicensed practice re Shaney Shoengarth. She will call me back with case #, etc.
27. 12-19-2002 T/C to Dr. Heye. Left message for contact.
28. 12-19-2002 T/C to Jim Smith, Chief Investigator, MQAC. Per Jim, Guideline information is public record, and I can give him a copy of it.
29. 12-19-2002 T/C to Eric Moore. Left message for contact.
30. 12-19-2002 T/C from Eric Moore. Discussed MQAC guidelines and policies, etc. Explained to Eric I plan to come by his office. He is requesting information of how our department validates complaints, etc.
31. 12-19-2002 T/C to Dave. Explained case, etc.

32. 12-19-2002 F/V to Laser Works. Met with Eric Moore. Eric had ?'s. Per Eric, he says he is going to find a way to beat this. Explained that this is nothing personal and again what my position is as an investigator.
- Per Eric, he states they are not providing medical treatment in any way and it should not be considered medical treatment.
33. 12-19-2002 Researched the Internet re:lasers. T/C to the laser companies. Rep will fax me a copy of the FDA standards, etc.
34. 12-19-2002 Reviewed some of the Internet website information with Jim.
35. 12-19-2002 Obtained Lidocaine information from Joe in Pharmacy. Copied for case file.
36. 12-19-2002 T/C to Dr. Fisher to verify we are still meeting at 6:15 AM tomorrow morning.
37. 12-20-2002 Prepared for and met witness Dr. Fisher. Showed Dr. Fisher the forms being used at Laser Works. Dr. Fisher became emotional after reviewing the forms I showed him. Dr. Fisher signed the Witness Notification form and discussed how concerned he is with how this investigation could affect his license to practice. Dr. Fisher states he will prepare and provide a statement for these investigations.
38. 12-20-2002 After returning to the office. Discussed interview with unlicensed Program Manager, etc.
39. 12-20-2002 Received faxed documents from Kathy Maynor/Lumenis company. Looked over documents, which include FDA information.
40. 12-23-2002 Received Notice of Appearance from R's attorney.
41. 12-23-2002 T/C from R's attorney.
42. 12-23-3002 T/C to R's attorney. Discussed case. Attorney is requesting a 7-day extension. He states he still has not talked to the R.
- Discussed case with Attorney and explained the complaint alleges all three respondents are practicing medicine without licensure. Attorney states he has not spoken with Dr. Fisher, only with Eric Moore, owner. He says Mr. Moore wants to cooperate and make things right. Attorney says he will speak with respondents and contact me.
43. 12-23-2002 Received statement of Dr. Fisher, witness, listed medical director of Laser Works. Reviewed statement.
44. 12-23-2002 Received E-mail from Kathy Maynor. Reviewed E-mail, etc.
45. 12-23-2002 T/C to Kathy Maynor. Left message for contact and thank her for the fax

46. 12-23-2002 Prepared memo to File of Interview conducted with Eric Moore, owner of Laser Works.
47. 12-23-2002 Prepared Memo to File of interview conducted with Dr. Fisher.
48. 12-23-2002 T/C to Chyma Miller-Smith, Unlicensed Program Manager. Discussed statement obtained.
49. 12-23-2002 Organized the file and reviewed all information obtained.
50. 12-24-2002 Received E-mail from Dr. Fisher. Reviewed and replied
51. 12-24-2002 T/C from Dr. Fisher. He says he went into Laser Works and brought a letter to Eric Moore personally to have his name removed as Medical Director. Dr. Fisher says he is concerned as he witnessed the employees appearing to still be treating patients/clients/customers. He is going to put this in writing.
52. 12-30-2002 Received original letter from R's attorney for all 3 R's. Reviewed letter.
53. 12-30-2002 T/C to Attorney. Left message. Placed in file.
54. 12-30-2002 T/C from R's attorney. He had a lot of ?'s. Attorney has never worked a case like this before. Explained the License Notification letter, etc. Attorney wanted to know process, etc. He also was requesting how Laser Works could get in compliance if found not in compliance. I explained he would have to contact the Medical Quality Assurance Commission, etc.
55. 01-03-2003 T/C from R's attorney on voice mail.
56. 01-03-2003 T/C to R's attorney. He had a lot of questions. Discussed case, etc. again. Gave him telephone numbers for Medical and Unlicensed Program, etc
57. 01-07-2003 T/C from R's attorney. ?'s.
58. 01-14-2003 E-mailed Dr. Fisher. He previously stated he would provide an additional statement from his office visit to Laser Works on 12/23/02. Received E-mail back from Dr. Fisher he would prepare statement and get to me by the end of the week.
59. 01-14-2003 Started the Investigative Report.
60. 01-15-2003 Received E-mail statement from Dr. Fisher. Reviewed statement. Replied to E-mail.
61. 01-15-2003 Prepared for meeting with R's attorney.
62. 01-15-2003 F/V to R's attorney's office. Went over R's written response, etc. Attorney had ?'s. Answered some questions, with Atty, contacted Chyma

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- attorney's
Miller-Smith, unlicensed program manager. After telephone call. Again, discussed additional information with R's attorney. After leaving office, reviewed information obtained.
63. 01-21-2003 T/C from R's attorney. Atty wanted to verify what I am requesting on the subpoena. Explained that I will need a variety of treatment provided, but he could give me an assortment of between 2-3 people seen per day from the date requested. Explained to Atty that I will need records and files for all people seen on December 23, 2002.
- Atty asked if they could just provide a typed version of the appointment book so I can see the names of the patients. Explained I need the copies of the actual appointment book pages.
- Atty asked do I only need the page of the treatment provided that day. Explained to Atty that I need the entire individual record.
64. 01-22-2003 T/C from R's attorney. Atty wanted to verify what I am requesting on the subpoena. Explained that I will need a variety of treatment provided, but he could give me an assortment of between 2-3 people seen per day from the date requested. Explained to Atty that I will need records and files for all people seen on December 23, 2002.
- Atty asked if they could just provide a typed version of the appointment book so I can see the names of the patients. Explained I need the copies of the actual appointment book pages.
- Atty asked do I only need the page of the treatment provided that day. Explained to Atty that I need the entire individual record.
65. 01-22-2003 T/C from R's attorney. Attorney gave the MD's information for Elizabeth Bianchi. Per Atty, MD is also the Medical Director for Nouveau of Spokane. Per Atty, he does not think Dr. Bianchi has an actual written contract and that contract is currently only verbal for Laser Works of Seattle. He says Dr. is aware of the complaints, etc. She may be difficult to reach today as she will be with patients most of the day.
66. 01-24-2003 T/C from R's attorney, early evening. R says he has all the information requested by subpoena ready. ? Of arrangements to meet and go over this information.
67. 01-24-2003 T/C on 1/26 to Attorney. Left message on his office # that I would be available to meet with him sometime on Monday, and to contact me.
68. 01-27-2003 T/C from R's attorney. Made arrangements to meet him and review requested subpoena documents.
69. 01-27-2003 F/V and met with R's attorney. Reviewed information obtained, etc. Attorney had ?'s.

70. 01-31-2003 T/C to new medical director, Dr. Bianchi. Discussed case and her involvement with Laser Works. Gave Dr. Bianchi web sites to obtain information regarding the lasers to include FDA information. She has the MQAC Guidelines she obtained from Eric, etc. Gave Dr. Bianchi the MQAC consultant's name and telephone number and also the Unlicensed Program Manager's name and # for contact. She says she is aware that she is responsible for the employees and what they are doing. She says she has reviewed the statements the three provided to me.
71. 02-13-2003 T/C from R's attorney on voice mail.
72. 02-13-2003 T/C to R's attorney. He had ?'s.
73. 02-18-2003 Worked on the Investigative Report.
74. 02-18-2003 T/C to C. Discussed his complaint.
75. 02-19-2003 Worked on the Investigative Report. Stamped evidence.
76. 02-19-2003 Reviewed all patient treatment records obtained from Laser Works, Inc.
77. 02-20-2003 Worked on the Investigative Report.
78. 02-21-2003 Finished the Investigative Report. Printed out the Investigative Report.
79. 02-21-2003 Prepared extension to program. Closed out case file.

APPENDIX H
REQUEST FOR INVESTIGATION

**DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION**

**CONFIDENTIAL INVESTIGATION REPORT
PREPARED FOR THE
SECRETARY, DEPARTMENT OF HEALTH**

Case # 2002-12-0013UI

RESPONDENT: SHANEY SHOENGARTH

(Companion Case #2002-08-0019UI Winterstein & #2002-09-0004UI Gelnette)

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Investigator: Gayle M. Crowley
Health Care Investigator

APPROVED BY _____ DATE _____

APPENDIX A

RESPONDENT INFORMATION

NAME: SHANEY SHOENGARTH

BUSINESS ADDRESS: 411 Strander Blvd., Suite 108
Tukwila, WA 98188

BUSINESS TELEPHONE #: (206) 575-8300

RESIDENCE ADDRESS: N/A

RESIDENCE TELEPHONE #: N/A

LICENSE NUMBER: Unlicensed

DATE ISSUED: N/A

EXPIRATION DATE: N/A

BIRTH DATE: N/A

SPECIALIZATION: N/A

PREVIOUS COMPLAINT HISTORY: 0/0

ATTORNEY IDENTIFICATION: Stephan O. Fjelstad, PLLC

APPENDIX B

COMPLAINANT INFORMATION

NAME: DOH

BUSINESS ADDRESS: N/A

BUSINESS TELEPHONE #: N/A

RESIDENCE ADDRESS: N/A

RESIDENCE TELEPHONE #: N/A

ATTORNEY: N/A

ATTORNEY ADDRESS: N/A

ATTORNEY TELEPHONE #: N/A

APPENDIX C
CONTACT LIST

John A. Fisher, MD
33C Etruria Street
Seattle, WA 98109
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(206) 205-2410 Work
(206) 680-7752 Pager

Eric Moore
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Tukwila, WA 98188
(206) 575-8300
(206) 501-7710 Cell

George Heye, MD
Medical Consultant
Medical QA Commission
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P. O. Box 47874
Olympia, WA 98504
(360) 236-4795

Kathy Maynor
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Rosie McGrew
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APPENDIX D

GENERAL SUMMARY

THE INFORMATION CONTAINED IN THIS REPORT, WITH IT'S ACCOMPANYING EVIDENCE AND EXHIBITS, SHOULD BE CONSIDERED IN CONJUNCTION WITH THAT INFORMATION INCLUDED IN THE COMPANION CASE FILES FOR THE MATTER REFERENCED ABOVE ON THE COVER PAGE OF THIS REPORT.

This investigation was initiated by receipt of two other complaints at the Unlicensed Program of the Department of Health. After a field visit was made to Laser Works, Inc., the respondent was identified as an employee performing the same job duties as the two companion case file respondents. On December 19, 2002, a request was made to conduct a field investigation to ascertain if the respondent is providing any type of medical services, which require licensure.

On September 17, 2002, a telephone interview was conducted with the complainant of the companion case file. She provided names of patients and also gave information regarding Laser Works and how the business is run.

On October 22, 2002, information was obtained from the Internet website for the State of Washington Cosmetology Board, including the requirements for licensure. This is listed as Evidence Pages 3-12 in the companion case file.

On December 17, 2002, information about laser treatment and equipment from various agencies was obtained from the Department of Health, Unlicensed Program Manager. This is listed as Evidence Pages 13-20 in the companion case file.

On December 17, 2002, a telephone interview was conducted with Dr. John Fisher, medical director of Laser Works, Inc. Dr. Fisher was not aware an investigation was open. He became the medical director to help the company with financing of the laser. He doesn't have much contact with the business, but does receive a monthly check for \$500 for them to use him as *their medical director*.

Dr. Fisher states in the three years he has been involved in the business, he was only called to see someone once, just after the business opened. He has not been to the business in at least six months and has not worked with or know any of the employees working at the Laser Works.

Dr. Fisher is full time employed as the Public Medical Doctor for King County, in the jail systems at different locations. It is his understanding the owners of Laser Works, Inc. have nurses providing treatment in their offices. He is unaware of any non-medical personnel providing treatment to patients.

Dr. Fisher explained he ordered lidocaine (later identified as 5% topical) for the business and the prescriptions were mailed directly to Laser Works. A Memo To File was prepared from this interview. This is listed as Evidence Page 31 in the companion case file.

On December 17, 2002, a field visit was made to the respondent's place of employment, Laser Works, Inc., with health care investigator Jim Voiland. Pictures were taken of the front reception office, treatment rooms, equipment being used for treatment, and framed posters.

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An interview was conducted with owner Eric Moore. Mr. Moore states his employees are not performing any medical treatment to individuals who come in for their services. He identified these individuals as clients or customers.

Mr. Moore says they did not hire Dr. Fisher to be the medical director out of necessity. They hired Dr. Fisher so they could have him order the lasers and obtain easier and better financing. Dr. Fisher was mainly a figurehead for the financing, and had little to do with the day-to-day operations of the business.

Mr. Moore says this office has seen 1,000's of people. The employees have been trained by the companies on how to work the lasers. He says nothing the employees do when working with the lasers require a physician or nurse. He identified the companion case file respondent as being a cosmetologist and that she started working her in June 2002. They usually do the intakes on all incoming patients/clients/customers. They find out which areas and describe the process and costs.

When Mr. Moore was asked about the respondent and companion case respondents using prescription strength lidocaine on patients/clients/customers, he says lidocaine is only given to someone in pain that requests it. He says it's not a big deal. He couldn't remember the last time they received any lidocaine, but says it is rarely used. He faxes a request to Dr. Fisher, who then orders it and it is delivered by mail to the business. Mr. Moore was unable to show us a container of lidocaine or where it is stored in the office, when asked, but walked around the office and opened cabinet doors.

Mr. Moore described the four lasers being used. He says they do have a microdermabrasion machine, but do very few treatments. Even though botox treatments are listed on Laser Works forms, he says this office does not perform these treatments. A Memo to File was prepared from this interview.

A copy of all Laser Works forms and brochures, located in the front reception office, were obtained. A review of these forms included the following:

- Reminder and Referrals – This form includes the following comment: "Following a botox treatment you should see improvements within 72 hours..."
- Informed Consent Form – Per owner Eric Moore, this is the new form they are using. This form first sentence reads, "I understand that I will receive medical treatment From Laser Works of Seattle."
- Patient Medical History
- Patient Medical History – Vascular Treatment
- Post Treatment – Vascular
- Pre-Treatment – Vascular
- Treatment Log
- Medical History – Skin Rejuvenation

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- Informed Consent – Microdermabrasion
- Informed Consent – Skin Rejuvenation
- Client Information Skin Rejuvenation
- Skin Rejuvenation (IPL) Post Treatment Care

A review was made of Laser Works appointment book. A sample of files were obtained, including individuals previously identified by the companion case file complainants. This is listed as Evidence Pages 32-134 in the companion case file.

On December 17, 2002, Dr. Fisher faxed a copy of his resignation as Medical Director for Laser Works, Inc. A telephone message for Dr. Fisher verified this letter was also faxed to Eric Moore at his home, per Mr. Moore's request. This is listed as Evidence Page 138 of the companion case file.

On December 18, 2002, a copy of the Medical Quality Assurance Commission's Policy was obtained from Dr. Heye. This is listed as Evidence Pages 139-140 of the companion case file.

On December 19, 2002, information regarding the drug, 5% Xylocaine (Lidocaine) was obtained from the 1997 Edition of the Physicians' Desk Reference. This is listed as Evidence Page 141 of the companion case file.

On December 19, 2002, an attempt was made to deliver the letter to the respondent explaining the allegations of unlicensed practice. When I requested to meet with the respondent, owner Eric said the respondent was providing treatment to someone. He requested the letter be left with him and he would be sure she received it. **Pages 1-3**

On December 19, 2002, information was obtained from several Internet Websites, including the Federal Drug Administration (FDA), and copies printed. Further contact was made with Kathy Maynor at Altus Medical. Ms. Maynor faxed laser FDA information. She also provided the explanations showing how the lasers are categorized, who can buy them, and who can use them. This is listed as Evidence Pages 142-184 of the companion case file.

On December 20, 2002, an interview was conducted with Dr. John Fisher. Dr. Fisher provided documents he had pertaining to his association and agreements with owners Eric Moore and Jeff Schmidt of Laser Works. These documents include copies of laser lease agreements.

During this interview, Dr. Fisher signed a Witness Notification Form. He expressed his concern about the investigation and how it could affect his license to practice. This is listed as Evidence Pages 185-204 of the companion case file.

On December 23, 2002, a Notice of Appearance was received from the respondent's attorney, Stephan Fjelstad. Mr. Fjelstad is also representing the two companion case file respondents. **Page 4**

During the course of conducting this investigation, Dr. Fisher provided correspondence by E-mail. Dr. Fisher also faxed a copy of the termination of the laser leasing agreement between

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himself, Jeff Schmidt, and Eric Moore. This is listed as Evidence Pages 206-214 in the companion case file.

On January 15, 2003, Dr. Fisher provided a statement. He described in detail how he became the medical director of Laser Works, Inc. Dr. Fisher said he was paid primarily to compensate him for the risk of putting his name on the lease of the ESC Alexandrite laser.

Dr. Fisher says he was never involved in the planning or set up of the clinic or the day-to-day running of the clinic. It was his understanding the laser work was to be done by RN's. In the several years he has been the medical director, Dr. Fisher says he has been called only once, during the first year of operation.

Dr. Fisher also discusses his ordering of the prescription for Lazercaine, a topical anesthetic of 5% lidocaine. This is listed as Evidence Pages 215-216 in the companion case files.

On January 15, 2003, the respondent's attorney provided the respondent's written response. This written response is the same one as for the two companion case file respondents. The respondent's attorney describes in detail how Laser Works, Inc. is performing its operations at the Tukwila location. He says prior to the business opening it's door, the principals diligently explored statutory licensing and regulations in Washington.

The respondent's attorney describes treatment provided by employees at Laser Works and says the nature of their services is strictly cosmetic. He says none of the employees diagnose or offer advice related to health problems. Customers simply want to enhance their appearance.

The respondent's attorney says the respondent has worked for Laser Works for nearly three years and has close to four years of experience with laser and pulsed light equipment.

The respondent's attorney states none of the employees, including the respondent, have ever prescribed or dispensed any drug or medicine for internal use to any customer. He denies any employees have stored or supplied any lidocaine at the premises, and have no intention of acquiring more for any purpose. He says the last time Laser Works received lidocaine was several months ago when a small shipment of fifteen containers were ordered. The respondent's attorney says the lidocaine was supplied to a tiny fraction of Laser Works customers to be applied to their skin prior to treatments.

The respondent's attorney explains Dr. Fisher's role as medical director for Laser Works, Inc. He says Dr. Fisher has never, to their knowledge, prescribed drugs or medicines to any customers.

The respondent's attorney denies the services Laser Works and their employees are providing qualify as the practice of medicine under Washington State law.

The respondent completed the Licensing Requirement Notification form by signing and also providing a written statement. **Pages 5-16**

On January 27, 2003, patient treatment records were obtained by subpoena. These were a sampling of records for individuals receiving treatment from December 17, 2002 through January 15, 2003. **Page 17**

A review of the records indicates several patients/clients/customers were given lazercaine (lidocaine) during the treatment process. This is noted on Evidence Page #411, and Evidence Page #621. A comment from the treatment provider suggesting lidocaine is listed on Evidence Page #455. These records are listed as Evidence Pages 230-683 in the companion case file.

On January 27, 2003, the respondent's attorney provided copies of three forms that have been revised and are being used at Laser Works. They are as follows:

- Customer Comments and Concerns
- Informed Consent Form
- Client Medical History

These forms are listed as Evidence Pages 684-687 in the companion case file

On January 31, 2003, a telephone interview was conducted with Dr. Elizabeth Bianchi. She states she is currently the medical director for Laser Works Inc. Dr. Bianchi states she is also the medical director of Nouveau (sp?) of Spokane. She says she lives and works in Spokane, but has made a visit to Laser Works. She also works for Planned Parenthood in Spokane. Dr. Bianchi said she understands she is responsible for the day to day treatment being provided at Laser Works, and is going to work with the Medical Quality Assurance Commission.

APPENDIX E

EVIDENCE & ATTACHMENTS

<u>Page #'s</u>	<u>Description</u>
1-3	Unlicensed letter delivered to respondent.
4	Notice of Appearance from the respondent's attorney, Stephan Fjelstad.
5-15	Respondent's written response signed and submitted by respondent's attorney.
16	Licensing Requirement Notification form signed by the respondent.
17	Subpoena request for appointment schedules and records.

APPENDIX F
POSSIBLE VIOLATIONS

18.130.190

APPENDIX G
ACTIVITY REPORT

1. 12-17-2002 T/C to Chyma, Unlicensed Program Manager. She will fax information to me on laser equipment and use, etc.
2. 12-17-2002 Received faxed information. Reviewed information received.
3. 12-17-2002 T/C to Jim Voiland, regarding meeting me this AM at Laser Works.
4. 12-17-2002 T/C to Dr. Heye, MQAC consultant. Discussed case, etc., and what information the MQAC has regarding any policy with lasers and who can provide laser treatment. Made arrangements to obtain this information from him when I come down to Olympia on December 18, 2002.
5. 12-17-2002 T/C to the Medical Director, Dr. Fisher. Left a message for him to contact me.
6. 12-17-2002 T/C from Dr. Fisher. Conducted a partial telephone interview with Dr. Fisher regarding his role and part with Laser Works. Dr. Fisher is going to fax me a copy of the resignation he is sending to Laser Works and Eric Moore. Made arrangements to meet with Dr. Fisher on 12/20 at 6:15 AM.
7. 12-17-2002 Met up with Jim and conducted an unannounced F/V to Laser Works.

Met with Eric Moore and discussed information, etc. Viewed the offices and equipment and took pictures of the equipment. Obtained evidence and documents from office. Obtained patient files from office to copy and return to the office.
8. 12-17-2002 Made copies back at the Kent office and returned the files to Laser Works. When I returned, Eric Moore had more ?'s.
9. 12-19-2002 T/C to Chyma. ?'s after reviewing guidelines. Can I give Eric Moore a copy of this, etc. Per Chyma, yes, but to clear with Medical. Also, they are in process of opening complaint on other unlicensed practice re Shaney Shoengarth. She will call me back with case #, etc.
10. 12-19-2002 T/C from Chyma, Program Manager. She provided the opened case #.
11. 12-19-2002 T/C to Dr. Heye. Left message for contact.
12. 12-19-2002 T/C to Jim Smith, Chief Investigator, MQAC. Per Jim, Guideline information is public record, and I can give him a copy of it.
13. 12-19-2002 T/C to Eric Moore. Left message for contact.

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14. 12-19-2002 T/C from Eric Moore. Discussed MQAC guidelines and policies, etc. Explained to Eric I plan to come by his office. He is requesting information of how our department validates complaints, etc.
15. 12-19-2002 T/C to Dave. Explained case, etc.
16. 12-19-2002 F/V to Laser Works. Met with Eric Moore. Eric had ?'s. Per Eric, he says he is going to find a way to beat this. Explained that this is nothing personal and again what my position is as an investigator.
- When I requested to meet with Shaney, Eric said she was providing treatment to someone. I left her letter with Eric.
- Per Eric, he states they are not providing medical treatment in any way and it should not be considered medical treatment.
17. 12-20-2002 Prepared for and met witness Dr. Fisher. Showed Dr. Fisher the forms being used at Laser Works. Dr. Fisher became emotional after reviewing the forms I showed him. Dr. Fisher signed the Witness Notification form and discussed how concerned he is with how this investigation could affect his license to practice. Dr. Fisher states he will prepare and provide a statement for these investigations.
18. 12-20-2002 After returning to the office. Discussed interview with unlicensed Program Manager, etc.
19. 12-20-2002 Received faxed documents from Kathy Maynor/Lumenis company. Looked over documents, which include FDA information.
20. 12-20-2002 T/C from attorney. He left a message he is now representing R's in the unlicensed case, on voice mail.
21. 12-20-2002 T/C to attorney. Left message that I will be in the office on Monday morning. Explained I will need a Notice of Appearance from him.
22. 12-23-2002 Received Notice of Appearance from R's attorney.
23. 12-23-2002 T/C from R's attorney.
24. 12-23-2002 T/C to R's attorney. Discussed case. Attorney is requesting a 7-day extension. He states he still has not talked to the R. Discussed case with Attorney and explained the complaint alleges all three respondents are practicing medicine without licensure. Attorney states he has not spoken with Dr. Fisher, only with Eric Moore, owner. He says Mr. Moore wants to cooperate and make things right. Attorney says he will speak with respondents and contact me.
25. 12-23-2002 Received statement of Dr. Fisher, witness, listed medical director of Laser Works. Reviewed statement.
26. 12-23-2002 Received E-mail from Kathy Maynor. Reviewed E-mail, etc.

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27. 12-23-2002 T/C to Kathy Maynor. Left message for contact and thank her for the fax.
28. 12-23-2002 Prepared memo to File of Interview conducted with Eric Moore, owner of Laser Works.
29. 12-23-2002 Prepared Memo to File of interview conducted with Dr. Fisher.
30. 12-23-2002 T/C to Chyma Miller-Smith, Unlicensed Program Manager. Discussed statement obtained.
31. 12-23-2002 Organized the file and reviewed all information obtained.
32. 12-24-2002 Received E-mail from Dr. Fisher. Reviewed and replied.
33. 12-24-2002 T/C from Dr. Fisher. He says he went into Laser Works and brought a letter to Eric Moore personally to have his name removed as Medical Director. Dr. Fisher says he is concerned as he witnessed the employees appearing to still be treating patients/clients/customers. He is going to put this in writing.
34. 12-30-2002 Received original letter from R's attorney for all 3 R's. Reviewed letter.
35. 12-30-2002 T/C to Attorney. Left message. Placed in file.
36. 12-30-2002 T/C from R's attorney. He had a lot of ?'s. Attorney has never worked a case like this before. Explained the License Notification letter, etc. Attorney wanted to know process, etc. He also was requesting how Laser Works could get in compliance if found not in compliance. I explained he would have to contact the Medical Quality Assurance Commission, etc.
37. 12-31-2002 Received case file. Case is already logged in. Companion to Case #2002-09-0004UI and Case #2002-08-0019UI
38. 01-03-2003 T/C from R's attorney. R had a lot of ?'s. Tried to answer questions relating to complaint, etc. Explained he would have to contact unlicensed program manager and MQAC consultant for answers. Per R's attorney, he has not spoken to Dr. Fisher to date.
39. 01-07-2003 T/C from R's attorney. ?'s.
40. 01-14-2003 E-mailed Dr. Fisher. He previously stated he would provide an additional statement from his office visit to Laser Works on 12/23/02. Received E-mail back from Dr. Fisher he would prepare statement and get to me by the end of the week.
41. 01-15-2003 Received E-mail statement from Dr. Fisher. Reviewed statement. Replied to E-mail.
42. 01-15-2003 Prepared for meeting with R's attorney.

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43. 01-15-2003 F/V to R's attorney's office. Went over R's written response, etc. Attorney had ?'s. Answered some questions, with Atty, contacted Chyma Miller-Smith, unlicensed program manager. After telephone call. Again, discussed additional information with R's attorney.
44. 01-15-2003 After leaving attorney's office, reviewed information obtained.
45. 01-21-2003 T/C from R's attorney. Per Atty, they have a new Medical Director. Dr. Elizabeth Bianchi.
46. 01-21-2003 T/C to unlicensed program manager, Chyma. She looked up ASI, Dr. Bianchi is located in Spokane, WA. Obtained information.
47. 01-21-2003 T/C to (509) 326-2142. This is a Planned Parenthood office. Per office staff, Dr. Bianchi works here one day a week. They provided her other office telephone #(509) 747-2902.
48. 01-21-2003 T/C to (509) 747-2902. Left message on voice mail for Dr. Bianchi.
49. 01-21-2003 T/C to R's attorney. Left message that I am requesting information regarding the new Medical Director Dr. Bianchi.
- 50.. 01-22-2003 T/C from R's attorney. Attorney gave the MD's information for Elizabeth Bianchi. Per Atty, MD is also the Medical Director for Nouveau of Spokane. Per Atty, he does not think Dr. Bianchi has an actual written contract and that contract is currently only verbal for Laser Works of Seattle. He says Dr. is aware of the complaints, etc. She may be difficult to reach today as she will be with patients most of the day.
51. 01-22-2003 T/C from R's attorney. Atty wanted to verify what I am requesting on the subpoena. Explained that I will need a variety of treatment provided, but he could give me an assortment of between 2-3 people seen per day from the date requested. Explained to Atty that I will need records and files for all people seen on December 23, 2002. Atty asked if they could just provide a typed version of the appointment book so I can see the names of the patients. Explained I need the copies of the actual appointment book pages. Atty asked do I only need the page of the treatment provided that day. Explained to Atty that I need the entire individual record.
52. 01-24-2003 T/C from R's attorney, early evening. R says he has all the information requested by subpoena ready. ? Of arrangements to meet and go over this information.
53. 01-24-2003 T/C on 1/26 to Attorney. Left message on his office # that I would be available to meet with him sometime on Monday, and to contact me.
54. 01-27-2003 T/C from R's attorney. Made arrangements to meet him and review requested subpoena documents.

55. 01-27-2003 F/V and met with R's attorney. Reviewed information obtained, etc. Attorney had ?'s.
56. 01-31-2003 T/C to new medical director, Dr. Bianchi. Discussed case and her involvement with Laser Works. Gave Dr. Bianchi web sites to obtain information regarding the lasers to include FDA information. She has the MQAC Guidelines she obtained from Eric, etc. Gave Dr. Bianchi the MQAC consultant's name and telephone number and also the Unlicensed Program Manager's name and # for contact. She says she is aware that she is responsible for the employees and what they are doing. She says she has reviewed the statements the three provided to me.
57. 02-13-2003 T/C from R's attorney on voice mail.
58. 02-13-2003 T/C to R's attorney. He had ?'s.
59. 02-18-2003 Worked on the Investigative Report.
60. 02-18-2003 T/C to C, companion case file. Discussed his complaint.
61. 02-20-2003 Worked on the Investigative Report.
62. 02-21-2003 Finished the Investigative Report. Stamped evidence. Closed out case file.

APPENDIX H
REQUEST FOR INVESTIGATION

**DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION**

**CONFIDENTIAL INVESTIGATION REPORT
PREPARED FOR THE
SECRETARY, DEPARTMENT OF HEALTH**

Case # 2002-08-0019UI

RESPONDENT: CHERI WINTERSTEIN

(Companion Case # 2002-09-0004UI Gelnette & #2002-12-0013UI Shoengarth)

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Investigator: Gayle M. Crowley
Health Care Investigator

APPROVED BY _____ DATE _____

APPENDIX A

RESPONDENT INFORMATION

NAME: SHERRY WINTERSTEIN

BUSINESS ADDRESS: 411 Strander Blvd., Suite 108
Tukwila, WA 98188

BUSINESS TELEPHONE #: (206) 575-8300

RESIDENCE ADDRESS: N/A

RESIDENCE TELEPHONE #: N/A

LICENSE NUMBER: Unlicensed

DATE ISSUED: N/A

EXPIRATION DATE: N/A

BIRTH DATE: N/A

SPECIALIZATION: N/A

PREVIOUS COMPLAINT HISTORY: 0/0

ATTORNEY IDENTIFICATION: Stephan O. Fjelstad, PLLC

APPENDIX B

COMPLAINANT INFORMATION

NAME: Anonymous

BUSINESS ADDRESS: N/a

BUSINESS TELEPHONE # : N/A

RESIDENCE ADDRESS: N/A

RESIDENCE TELEPHONE # : N/A

ATTORNEY: N/A

ATTORNEY ADDRESS: N/A

ATTORNEY TELEPHONE # : N/A

APPENDIX C
CONTACT LIST

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Gayle M. Crowley
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APPENDIX D

GENERAL SUMMARY

THE INFORMATION CONTAINED IN THIS REPORT, WITH IT'S ACCOMPANYING EVIDENCE AND EXHIBITS, SHOULD BE CONSIDERED IN CONJUNCTION WITH THAT INFORMATION INCLUDED IN THE COMPANION CASE FILES FOR THE MATTER REFERENCED ABOVE ON THE COVER PAGE OF THIS REPORT.

On August 30, 2002, the Unlicensed Program Manager received an anonymous call from a person who said they received laser hair removal treatment from the respondent at Laser Works of Seattle. The anonymous complainant alleges in talking with the respondent, she learned none of the employees are licensed healthcare providers. She also alleges the "medical director" John Fisher is never there and the respondent told her she had never seen or met him. *The complainant identified a cool glide Altus laser (class 3 or 4) as the tool the respondent used on her.*

The complainant had no ill effects from the procedure of hair removal from under her arms, but felt the respondent was unprofessional. She alleges the respondent did not wipe down the machine prior to using it on her.

The complainant says her health history was taken and she had to come back the next day for treatment as they were so booked up. *She said she went here because they were cheaper than going to a medical office, but she still assumed they had some kind of license until she was told otherwise.*

A search was made of the Internet and copies were made of website information. **Page 1-14**

On September 9, 2002, the Unlicensed Program requested a field investigation be conducted to verify if the respondent is providing any type of medical services for which requires licensure. **Page 15**

On September 17, 2002, a telephone interview was conducted with the complainant. *She provided names of patients and also gave information regarding Laser Works and how the business is run.*

On October 22, 2002, information was obtained from the Internet website for the State of Washington Cosmetology Board, including the requirements for licensure. This is listed as Evidence Pages 3-12 in the companion case file.

On December 16, 2002, a letter was delivered to the respondent and an interview was conducted. A telephone call was made to the respondent prior to arrival at Laser Works. The business was closing and the respondent said she would wait for my arrival. The respondent denied she is performing any type of medical treatment or practicing medicine. The respondent did not want to sign the Licensing Requirement Notification at this time. The respondent started crying and said she thought she was dying when I called and told her I was from the Department of Health and needed to meet with her.

The respondent's boss, called on the telephone. He identified himself as Eric Moore and said he was also the owner of Laser Works, Inc. A short time later, Mr. Moore requested I leave the office and contact him at a later date. **Pages 16-18**

On December 17, 2002, information about laser treatment and equipment from various agencies was obtained from the Department of Health, Unlicensed Program Manager. This is listed as Evidence Pages 13-20 in the companion case file.

On December 17, 2002, a telephone interview was conducted with Dr. John Fisher, medical director of Laser Works, Inc. Dr. Fisher was not aware an investigation was open. He became the medical director to help the company with financing of the laser. He doesn't have much contact with the business, but does receive a monthly check for \$500 for them to use him as their medical director.

Dr. Fisher states in the three years he has been involved in the business, he was only called to see someone once, just after the business opened. He has not been to the business in at least six months and has not worked with or know any of the employees working at the Laser Works.

Dr. Fisher is full time employed as the Public Medical Doctor for King County, in the jail systems at different locations. It is his understanding the owners of Laser Works, Inc. have nurses providing treatment in their offices. He is unaware of any non-medical personnel providing treatment to patients.

Dr. Fisher explained he ordered lidocaine (later identified as 5% topical) for the business and the prescriptions were mailed directly to Laser Works. A Memo To File was prepared from this interview. This is listed as Evidence Page 31 in the companion case file.

On December 17, 2002, a field visit was made to the respondent's place of employment, Laser Works, Inc., with health care investigator Jim Voiland. Pictures were taken of the front reception office, treatment rooms, equipment being used for treatment, and framed posters.

An interview was conducted with owner Eric Moore. Mr. Moore states his employees are not performing any medical treatment to individuals who come in for their services. He identified these individuals as clients or customers.

Mr. Moore says they did not hire Dr. Fisher to be the medical director out of necessity. They hired Dr. Fisher so they could have him order the lasers and obtain easier and better financing. Dr. Fisher was mainly a figurehead for the financing, and had little to do with the day-to-day operations of the business.

Mr. Moore says this office has seen 1,000's of people. The employees have been trained by the companies on how to work the lasers. He says nothing the employees do when working with the lasers require a physician or nurse. He identified the companion case file respondent as being a cosmetologist and that she started working her in June 2002. They usually do the intakes on all incoming patients/clients/customers. They find out which areas and describe the process and costs.

When Mr. Moore was asked about the respondent and companion case respondents using prescription strength lidocaine on patients/clients/customers, he says lidocaine is only given to someone in pain that requests it. He says it's not a big deal. He couldn't remember the last time they received any lidocaine, but says it is rarely used. He faxes a request to Dr. Fisher,

who then orders it and it is delivered by mail to the business. Mr. Moore was unable to show us a container of lidocaine or where it is stored in the office, when asked, but walked around the office and opened cabinet doors.

Mr. Moore described the four lasers being used. He says they do have a microdermabrasion machine, but do very few treatments. Even though botox treatments are listed on Laser Works forms, he says this office does not perform these treatments. A Memo to File was prepared from this interview.

A copy of all Laser Works forms and brochures, located in the front reception office, were obtained. A review of these forms included the following:

- *Reminder and Referrals* – This form includes the following comment: "Following a botox treatment you should see improvements within 72 hours..."
- *Informed Consent Form* – Per owner Eric Moore, this is the new form they are using. This form first sentence reads, "I understand that I will receive medical treatment From Laser Works of Seattle."
- *Patient Medical History*
- *Patient Medical History – Vascular Treatment*
- *Post Treatment – Vascular*
- *Pre-Treatment – Vascular*
- *Treatment Log*
- *Medical History – Skin Rejuvenation*
- *Informed Consent – Microdermabrasion*
- *Informed Consent – Skin Rejuvenation*
- *Client Information Skin Rejuvenation*
- *Skin Rejuvenation (IPL) Post Treatment Care*

A review was made of Laser Works appointment book. A sample of files were obtained, including individuals previously identified by the complainant and companion case file complainant. This is listed as Evidence Pages 32-134 in the companion case file.

On December 17, 2002, Dr. Fisher faxed a copy of his resignation as Medical Director for Laser Works, Inc. A telephone message for Dr. Fisher verified this letter was also faxed to Eric Moore at his home, per Mr. Moore's request. This is listed as Evidence Page 138 of the companion case file.

On December 18, 2002, a copy of the Medical Quality Assurance Commission's Policy was obtained from Dr. Heye. This is listed as Evidence Pages 139-140 of the companion case file.

On December 19, 2002, information regarding the drug, 5% Xylocaine (Lidocaine) was obtained from the 1997 Edition of the Physicians' Desk Reference. This is listed as Evidence Page 141 of the companion case file.

On December 19, 2002, information was obtained from several Internet Websites, including the Federal Drug Administration (FDA), and copies printed. Further contact was made with Kathy Maynor at Altus Medical. Ms. Maynor faxed laser FDA information. She also provided the explanations showing how the lasers are categorized, who can buy them, and who can use them. This is listed as Evidence Pages 142-184 of the companion case file.

On December 20, 2002, an interview was conducted with Dr. John Fisher. Dr. Fisher provided documents he had pertaining to his association and agreements with owners Eric Moore and Jeff Schmidt of Laser Works. These documents include copies of laser lease agreements.

During this interview, Dr. Fisher signed a Witness Notification Form. He expressed his concern about the investigation and how it could affect his license to practice. This is listed as Evidence Pages 185-204 of the companion case file.

On December 23, 2002, a Notice of Appearance was received from the respondent's attorney, Stephan Fjelstad. The respondent's first name was previously misspelled as Sherry instead of Cheri. Mr. Fjelstad is also representing the two companion case file respondents.

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During the course of conducting this investigation, Dr. Fisher provided correspondence by E-mail. Dr. Fisher also faxed a copy of the termination of the laser leasing agreement between himself, Jeff Schmidt, and Eric Moore. This is listed as Evidence Pages 206-214 in the companion case file.

On January 15, 2003, Dr. Fisher provided a statement. He described in detail how he became the medical director of Laser Works, Inc. Dr. Fisher said he was paid primarily to compensate him for the risk of putting his name on the lease of the ESC Alexandrite laser.

Dr. Fisher says he was never involved in the planning or set up of the clinic or the day-to-day running of the clinic. It was his understanding the laser work was to be done by RN's. In the several years he has been the medical director, Dr. Fisher says he has been called only once, during the first year of operation.

Dr. Fisher also discusses his ordering of the prescription for Lazercaine, a topical anesthetic of 5% lidocaine. This is listed as Evidence Pages 215-216 in the companion case files.

On January 15, 2003, the respondent's attorney provided the respondent's written response. This written response is the same one as for the two companion case file respondents. The respondent's attorney describes in detail how Laser Works, Inc. is performing its operations at the Tukwila location. He says prior to the business opening it's door, the principals diligently explored statutory licensing and regulations in Washington.

The respondent's attorney describes treatment provided by employees at Laser Works and says the nature of their services is strictly cosmetic. He says none of the employees diagnose or offer advice related to health problems. Customers simply want to enhance their appearance.

The respondent's attorney says the respondent has provided treatment with laser and pulsed light technology for over one year and also does dermabrasion at Laser Works.

The respondent's attorney states none of the employees, including the respondent, have ever prescribed or dispensed any drug or medicine for internal use to any customer. He denies any employees have stored or supplied any lidocaine at the premises, and have no intention of acquiring more for any purpose. He says the last time Laser Works received lidocaine was several months ago when a small shipment of fifteen containers were ordered. The respondent's attorney says the lidocaine was supplied to a tiny fraction of Laser Works customers to be applied to their skin prior to treatments.

The respondent's attorney explains Dr. Fisher's role as medical director for Laser Works, Inc. He says Dr. Fisher has never, to their knowledge, prescribed drugs or medicines to any customers.

The respondent's attorney denies the services Laser Works and their employees are providing qualify as the practice of medicine under Washington State law.

The respondent completed the Licensing Requirement Notification form by signing and also providing a written statement. **Pages 20-31**

On January 27, 2003, patient treatment records were obtained by subpoena. These were a sampling of records for individuals receiving treatment from December 17, 2002 through January 15, 2003. **Page 32**

A review of the records indicates several patients/clients/customers were given lazercaine (lidocaine) during the treatment process. This is noted on Evidence Page #411, and Evidence Page #621. A comment from the treatment provider suggesting lidocaine is listed on Evidence Page #455. These records are listed as Evidence Pages 230-683 in the companion case file.

On January 27, 2003, the respondent's attorney provided copies of three forms that have been revised and are being used at Laser Works. They are as follows:

- Customer Comments and Concerns
- Informed Consent Form
- Client Medical History

These forms are listed as Evidence Pages 684-687 in the companion case file

On January 31, 2003, a telephone interview was conducted with Dr. Elizabeth Bianchi. She states she is currently the medical director for Laser Works Inc. Dr. Bianchi states she is also the medical director of Nouveau (sp?) of Spokane. She says she lives and works in Spokane, but has made a visit to Laser Works. She also works for Planned Parenthood in Spokane. Dr. Bianchi said she understands she is responsible for the day to day treatment being provided at Laser Works, and is going to work with the Medical Quality Assurance Commission.

APPENDIX E

EVIDENCE & ATTACHMENTS

<u>Page #'s</u>	<u>Description</u>
1	Memorandum to File of anonymous complaint.
2-14	Internet website information.
15	Request for field investigation by Unlicensed Program Manager.
16-18	Unlicensed letter delivered to respondent.
19	Notice of Appearance from the respondent's attorney, Stephan Fjelstad.
20-28	Respondent's written response signed and submitted by respondent's attorney.
29	Licensing Requirement Notification form signed by the respondent.
30-31	Correspondence from the respondent's attorney.
32	Subpoena request for appointment schedules and records.

APPENDIX F
POSSIBLE VIOLATIONS

RCW 18.130.190

APPENDIX G
ACTIVITY REPORT

1. 09-16-2002 Received case file.
2. 09-16-2002 Reviewed case file. Field visit will be necessary. Additional Internet information was in file. Reviewed. This case is companion to #0004 UI case as same business office, but different respondent's.
3. 09-17-2002 Reviewed case and discussed with Lloyd and Jim.
4. 09-17-2002 Researched information.
5. 09-17-2002 T/C to C. Conducted interview with C over the telephone. C does not want to sign a Whistleblower. She was actually an employee of the business. She gave information regarding the business and how it is run. Former employee.
6. 09-17-2002 Looked up on the Internet and other information on ASI and also telephone book.
7. 09-17-2002 T/C to business. Obtained business hours, etc.
8. 10-22-2002 T/C to Chyma. ?'s concerning what an unlicensed can do regarding Laser, Chemical Peels, etc. She has had a case before, but not the same as these.
9. 10-22-2002 Looked up on the Internet information about the Cosmetology Board, etc. Printed the information.
10. 10-22-2002 T/C to the Cosmetology Board. Left message for contact with someone here.
11. 10-22-2002 T/C from Rosie, Cosmetology Board.
12. 12-16-2002 Prepared unlicensed letter to deliver to R at unannounced field visit to Laser Works.
13. 12-16-2002 T/C to Laser Works to find out what time they are opened until. It was 4:55PM. Per Sherry, they were closing at 5PM. I explained I was on my way and would like to meet with her. I asked if she would be willing to wait for me. Per Sherry, she said she would wait. I told her I was in traffic. When I arrived, I met with Sherry in one of Laser Works office's. I explained why I was out to see her about the allegations of unlicensed practice. The respondent starting crying and said she thought when I told her I was from the Department of Health, that meant she was dying or something. I apologized, and continued to explain why I was out to see her. While interviewing the R, the owner identified as Eric Moore called.

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He wanted to speak with me. I explained I was here to see the R. He said his employees are not practicing medicine, they are only removing hair. He hung up, but had another employee (later identified as Shaney) come in and tell me I had to leave.

14. 12-16-2002 After leaving, contacted Jim Voiland and discussed what I found, etc.
15. 12-16-2002 Wrote notes, etc.
16. 12-17-2002 T/C to Chyma, unlicensed Program Manager. She will fax information to me on laser equipment and use, etc.
17. 12-17-2002 Received faxed information. Reviewed.
18. 12-17-2002 T/C to Jim Voiland, regarding meeting me this AM at Laser Works.
19. 12-17-2002 T/C to Dr. Heye, MQAC consultant. Discussed case, etc., and what information the MQAC has regarding any policy with lasers and who can provide laser treatment. Made arrangements to obtain this information from him when I come down to Olympia on December 18, 2002.
20. 12-17-2002 T/C to the Medical Director, Dr. Fisher. Left a message for him to contact me.
21. 12-17-2002 T/C from Dr. Fisher. Conducted a partial telephone interview with Dr. Fisher regarding his role and part with Laser Works. Dr. Fisher is going to fax me a copy of the resignation he is sending to Laser Works and Eric Moore. Made arrangements to meet with Dr. Fisher on 12/20 at 6:15 AM.
22. 12-17-2002 Met up with Jim and conducted an unannounced F/V to Laser Works.
23. 12-17-2002 Met with Eric Moore and discussed information, etc. Viewed the offices and equipment and took pictures of the equipment.
24. 12-17-2002 Obtained evidence and documents from office. Obtained patient files from office to copy and return to the office.
25. 12-17-2002 Made copies back at the Kent office and returned the files to Laser Works. When I returned, Eric Moore had more ?'s.
26. 12-18-2002 Reviewed MQAC Policy on the Use of Lasers in Skin Care and Treatment, dated October 25, 2002. Made notes of ?'s to ask Dr. Heye.
27. 12-18-2002 Met with MQAC medical consultant, Dr. Heye and obtained copy of MQAC Policies of the use of Laser. Also met with MQAC Chief Investigator Jim Smith, discussed company's medical director and his part in the company, etc.
27. 12-19-2002 T/C to Chyma. ?'s after reviewing guidelines. Can I give Eric Moore a copy of this, etc. Per Chyma, yes, but to clear with Medical. Also, they

2002-08-0019UI / CHERI WINTERSTEIN

are in process of opening complaint on other unlicensed practice re Shaney Shoengarth. She will call me back with case #, etc.

- 28. 12-19-2002 T/C to Dr. Heye. Left message for contact.
- 29. 12-19-2002 T/C to Jim Smith, Chief Investigator, MQAC. Per Jim, Guideline information is public record, and I can give him a copy of it.
- 30. 12-19-2002 T/C to Eric Moore. Left message for contact.
- 31. 12-19-2002 T/C from Eric Moore. Discussed MQAC guidelines and policies, etc. Explained to Eric I plan to come by his office. He is requesting information of how our department validates complaints, etc.
- 32. 12-19-2002 T/C to Dave. Explained case, etc.
- 33. 12-19-2002 F/V to Laser Works. Met with Eric Moore. Eric had ?'s. Per Eric, he says he is going to find a way to beat this. Explained that this is nothing personal and again what my position is as an investigator.

When I requested to meet with Shaney, Eric said she was providing treatment to someone. I left her letter with Eric.

Per Eric, he states they are not providing medical treatment in any way And it should not be considered medical treatment.
- 34. 12-19-2002 Researched the Internet re: lasers. T/C to the laser companies. Rep will fax me a copy of the FDA standards, etc.
- 35. 12-19-2002 Reviewed some of the Internet website information with Jim.
- 36. 12-19-2002 Obtained Lidocaine information from Joe, Investigator, in Pharmacy. Copied for case file.
- 37. 12-19-2002 T/C to Dr. Fisher to verify we are still meeting at 6:15 AM tomorrow morning.
- 38. 12-20-2002 Prepared for and met witness Dr. Fisher. Showed Dr. Fisher the forms being used at Laser Works. Dr. Fisher became emotional after reviewing the forms I showed him. Dr. Fisher signed the Witness Notification form and discussed how concerned he is with how this investigation could affect his license to practice. Dr. Fisher states he will prepare and provide a statement for these investigations.
- 39. 12-20-2002 After returning to the office. Discussed interview with unlicensed Program Manager, etc.
- 40. 12-20-2002 Received faxed documents from Kathy Maynor/Lumenis company. Looked over documents, which include FDA information.

41. 12-23-2002 Received statement of Dr. Fisher, witness, listed medical director of Laser Works. Reviewed statement.
42. 12-23-2002 Received E-mail from Kathy Maynor. Reviewed E-mail, etc.
43. 12-23-2002 T/C to Kathy Maynor. Left message for contact and thank her for the fax.
44. 12-23-2002 Prepared memo to File of Interview conducted with Eric Moore, owner of Laser Works.
45. 12-23-2002 Prepared Memo to File of interview conducted with Dr. Fisher.
46. 12-23-2002 T/C to Chyma Miller-Smith, Unlicensed Program Manager. Discussed statement obtained.
47. 12-23-2002 Organized the file and reviewed all information obtained.
48. 12-23-2002 T/C from Dr. Heye.
49. 12-23-2002 T/C to Dr. Heye, MQAC. Explained I obtained the information from Jim Smith, MQAC.
50. 12-23-2002 Received Notice of Appearance from R's attorney.
51. 12-23-2002 T/C from R's attorney.
52. 12-23-2002 T/C to R's attorney. Discussed case. Attorney is requesting a 7-day extension. He states he still has not talked to the R.
- Discussed case with Attorney and explained the complaint alleges all three respondents are practicing medicine without licensure.
- Attorney states he has not spoken with Dr. Fisher, only with Eric Moore, owner. He says Mr. Moore wants to cooperate and make things right. Attorney says he will speak with respondents and contact me.
53. 12-24-2002 Received E-mail from Dr. Fisher. Reviewed and replied.
54. 12-24-2002 T/C from Dr. Fisher. He says he went into Laser Works and brought a letter to Eric Moore personally to have his name removed as Medical Director. Dr. Fisher says he is concerned as he witnessed the employees appearing to still be treating patients/clients/customers. He is going to put this in writing.
55. 12-30-2002 Received original letter from R's attorney for all 3 R's. Reviewed letter.
56. 12-30-2002 T/C to Attorney. Left message.
57. 12-30-2002 T/C from R's attorney. He had a lot of ?'s. Attorney has never worked a case like this before. Explained the License Notification letter, etc. Attorney wanted to know process, etc. He also was requesting how

Laser Works could get in compliance if found not in compliance. I explained he would have to contact the Medical Quality Assurance Commission, etc.

- 58. 01-03-2003 T/C from R's attorney. R had a lot of ?'s. Tried to answer questions relating to complaint, etc. Explained he would have to contact unlicensed program manager and MQAC consultant for answers. Per R's attorney, he has not spoken to Dr. Fisher to date.
- 59. 01-07-2003 T/C from R's attorney. ?'s.
- 60. 01-14-2003 E-mailed Dr. Fisher. He previously stated he would provide an additional statement from his office visit to Laser Works on 12/23/02. Received E-mail back from Dr. Fisher he would prepare statement and get to me by the end of the week.
- 61. 01-14-2003 Started the Investigative Report.
- 62. 01-15-2003 Received E-mail statement from Dr. Fisher. Reviewed statement.
- 63. 01-15-2003 Replied to E-mail.
- 64. 01-15-2003 Prepared for meeting with R's attorney.
- 65. 01-15-2003 F/V to R's attorney's office. Went over R's written response, etc. Attorney had ?'s. Answered some questions, with Atty, contacted Chyma Miller-Smith, unlicensed program manager. After telephone call. Again, discussed additional information with R's attorney.
- 66. 01-15-2003 After leaving attorney's office, reviewed information obtained.
- 67. 01-21-2003 T/C from R's attorney. Per Atty, they have a new Medical Director. Dr. Elizabeth Bianchi.
- 68. 01-21-2003 T/C to unlicensed program manager, Chyma. She looked up ASI, Dr. Bianchi is located in Spokane, WA. Obtained information.
- 69. 01-21-2003 T/C to (509) 326-2142. This is a Planned Parenthood office. Per office staff, Dr. Bianchi works here one day a week. They provided her other office telephone #(509) 747-2902.
- 70. 01-21-2003 T/C to (509) 747-2902. Left message on voice mail for Dr. Bianchi.
- 71. 01-21-2003 T/C to R's attorney. Left message that I am requesting information regarding the new Medical Director Dr. Bianchi.
- 72. 01-22-2003 T/C from R's attorney. Attorney gave the MD's information for Elizabeth Bianchi. Per Atty, MD is also the Medical Director for Nouveau of Spokane. Per Atty, he does not think Dr. Bianchi has an actual written contract and that contract is currently only verbal for Laser Works of Seattle. He says Dr. is aware of the complaints, etc. She may be difficult

to reach today as she will be with patients most of the day.

- 73. 01-22-2003 T/C from R's attorney. Atty wanted to verify what I am requesting on the subpoena. Explained that I will need a variety of treatment provided, but he could give me an assortment of between 2-3 people seen per day from the date requested. Explained to Atty that I will need records and files for all people seen on December 23, 2002. Atty asked if they could just provide a typed version of the appointment book so I can see the names of the patients. Explained I need the copies of the actual appointment book pages. Atty asked *do I only need the page of the treatment* provided that day. Explained to Atty that I need the entire individual record.
- 74. 01-24-2003 T/C from R's attorney, early evening. R says he has all the information requested by subpoena ready. ? Of arrangements to meet and go over this information.
- 75. 01-24-2003 T/C on 1/26 to Attorney. Left message on his office # that I would be available to meet with him sometime on Monday, and to contact me.
- 76. 01-27-2003 T/C from R's attorney. Made arrangements to meet him and review requested subpoena documents.
- 77. 01-27-2003 F/V and met with R's attorney. Reviewed information obtained, etc. Attorney had ?'s.
- 78. 01-31-2003 T/C to new medical director, Dr. Bianchi. Discussed case and her involvement with Laser Works. Gave Dr. Bianchi web sites to obtain information regarding the lasers to include FDA information. She has the MQAC Guidelines she obtained from Eric, etc. Gave Dr. Bianchi the MQAC consultant's name and telephone number and also the Unlicensed Program Manager's name and # for contact. She says she is aware that she is responsible for the employees and what they are doing. She says she has reviewed the statements the three provided to me.
- 79. 02-13-2003 T/C from R's attorney on voice mail.
- 80. 02-13-2003 T/C to R's attorney. He had ?'s.
- 81. 02-18-2003 Worked on the Investigative Report.
- 82. 02-18-2003 T/C to C, companion case file. Discussed his complaint.
- 83. 02-20-2003 Worked on the Investigative Report.
- 84. 02-21-2003 Finished the Investigative Report. Stamped evidence.
- 85. 02-21-2003 Prepared extension to program. Closed out case file.

APPENDIX H

REQUEST FOR INVESTIGATION



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

• P.O. Box 47866 • Olympia, Washington 98504-7866

September 11, 2003

Elizabeth A. Bianchi, MD
E 10808 46th
Spokane, WA 99206

Dear Dr. Bianchi:

SUBJECT: Elizabeth A. Bianchi, MD
Case No: 2002-12-0019MD

The Medical Quality Assurance Commission has completed its investigation regarding allegations of aiding or abetting unlicensed practice.

In order to take action, the Commission must prove that there were violations of rules or regulations governing the profession. After careful consideration of the records and information obtained during its investigation, it was determined that disciplinary action is not necessary.

As a reminder, you may submit an additional written statement if you wish it to be added to the case filed. The file will be subject to release within the guidelines established by Washington public disclosure laws. Public disclosure requests usually come from insurance companies and employers.

Thank you very much for your cooperation in this matter. If you have any questions, please feel free to contact me at (360)236-4792 or Lisa Noonan at (360)236-4791.

Respectfully,

COPY

MARYELLA JANSEN, Deputy Executive Director
Medical Quality Assurance Commission

**Department Of Health
Health Professions Quality Assurance Division
Washington State
Medical Quality Assurance Commission
Policy draft 7-7**

Title:	Use of Lasers in Skin Care and Treatment	Number: MD2003-02
Reference:		
Contact:	George Heye, MD	
Effective Date:		
Supersedes		
Approved		

BACKGROUND

The U.S. Food and Drug Administration regulates the sale of lasers¹. Lasers are prescription devices that can be sold only to licensed practitioners with prescriptive authority. Complications from the use of lasers for skin care and treatment include visual impairment, blindness, inflammation, burns, scarring, hypopigmentation and hyperpigmentation.

POLICY

1. The use of a laser to treat or alter the skin is the practice of medicine under RCW 18.71.011. Such use may be performed only by a physician licensed to practice medicine in the state of Washington, or by an allied health professional under the supervision of a physician license to practice medicine in the state of Washington.
2. The physician should be appropriately trained in the physics, safety and techniques of using lasers. Prior to initiating laser treatment, the physician should take a history, perform an appropriate physical examination, make an appropriate diagnosis, recommend appropriate treatment, obtain the patient's informed consent which includes informing the patient that a non-physician may operate the laser, provide instructions for emergency and follow-up care, and prepare an appropriate medical record.
3. A physician who meets the above requirements may delegate a laser procedure to an allied health professional, provided such delegation falls within the allied health professional's scope of practice. "Allied health professional" means a person licensed, certified, or registered to practice a profession

¹ The use of the word "laser" in this policy includes pulsed dye devices, intense pulsed light devices and radiofrequency generators.

governed by RCW 18.130. A physician making such delegation must prepare a written protocol for the allied health professional to follow in administering the laser treatment.

4. The supervising physician should ensure that the allied health professional has appropriate documented training in the area of basic dermatology and demonstrable training in the safe and effective use of a laser. The allied health professional may perform specifically designed laser procedures pursuant to the written protocol. The allied health professional may not act independently or exercise independent medical judgment in performing a laser procedure.

As the complexity of a skin condition increases, so should the involvement of a physician in the care of that patient. Procedures which carry unusual or significant risks based on the age of the patient, the diagnosis, or the location on the body, should either not be delegated at all or should be delegated only to allied health professionals whose skills and experience are commensurate with the problem. In some cases, the allied health professional may need significant medical training, such as that possessed by a registered nurse or a physician assistant.

5. The physician should provide appropriate supervision to the allied health professional. This may require that the supervising physician be on site or it may require that the supervising physician be reasonably available in person to deal with complications. This will depend on the facility, the patient, the diagnosis, the person providing the treatment and the nature of the treatment being provided. Reasonable care and safety of the patient, not physician convenience, is the standard.

6. Regardless of who performs the laser treatment, the physician is ultimately responsible for the safety of the patient.

BUSINESS NOTEBOOK

Nuvo skin clinic unveils new location

By Melodie Little

Staff writer

The co-owners of Nuvo recently completed a \$120,000 project that transformed a vacant store at the Spokane Valley Mall into a state-of-the-art laser skin clinic.

The renovation added an elegant marble facade, a reception area and separate procedure rooms.

"We needed to do everything inside to get it ready to go," said Jeffrey Gelnette, who owns 49 percent of the store with his wife, Sherri.

The other 51 percent of the co-venture is owned by parent company Nuvo International. The chain has clinics in four Western states, with three clinics currently operating in Washington. Business has been steady since the shop moved into its new location in mid-March, Gelnette said.

The new clinic replaces the temporary location that was upstairs, next to Gordon Jewelers.

Services offered at the clinic include botox injections to reduce wrinkles, photo facials and photo rejuvenation to remove age spots and other blemishes, laser hair removal, micro dermabrasion, spider vein therapy and tattoo removal. The laser therapy is particularly effective for small broken veins in the face, Gelnette said.

The clinic has 12 employees, including aestheticians and a licensed medical doctor who specializes in aesthetics.

Spray on tanning is available for \$25. It produces a uniform, streak-free tan that lasts around five days. Gelnette said the tanning is particularly popular with people who are attending upcoming special

events, such as weddings and reunions.

The clinic will soon offer teeth whitening for clients who have visited one of two approved dentists for preliminary check-ups and cleanings, Gelnette said.

Gelnette and his wife are also negotiating the lease of a site in the NorthTown Mall and hope to open a new clinic there by Aug. 1.

Gelnette's professional background gives him a unique business perspective. Years ago, he practiced law in Pennsylvania. He and his wife moved to North Idaho, where he served as the pastor of Coeur d'Alene Bible Church. After 20 years in the ministry, Gelnette and his wife were ready to shift gears.

He views his career change as an opportunity to help people improve their self-images. "People tend to think it's just something for vanity or beauty's sake," Gelnette said. "We want to do it properly and we want to help people. Our goal is to do it in an honorable way."

Farmers' market up and running

Susan Parker, one of the organizers of the Liberty Lake Farmers' Market, said the market has around 25 vendors and expects that number to increase once farmers start arriving with fresh produce in early June.

"We have some gals that have flowers and herbs. We have native plants," Parker said. "We have several people with vegetable plants and perennials."

Handcrafted items include wrought iron trellises and yard art, birdhouses, wooden benches, jewelry, soaps, lotions and quilted items. The market donates a tiny

space for kid-entrepreneurs, who want to sell their wares. Children must have signs and stick around the booth.

Parker said a small percentage of the vendors are established year-round businesses, such as Rockwood Bakery. Although there is a diverse assortment of vendors, the main focus of the market is getting fresh produce into the market for consumers to purchase.

The market is at 1421 N. Meadowwood Lane and is open Saturdays, from 9 a.m. to 1 p.m., through the end of September and possibly longer if fresh produce is still available. For more information, call 343-6000.

Aqua massage available at Mall

Baldwin Enterprises has opened Aqua Massage at a kiosk near the Spokane Valley Mall's west entrance.

Clients lie in massage beds as a rotating arm shoots pressurized water on their backs. The arm travels the length of the bed. A plastic drape allows customers to feel the pressure of the water without getting wet.

Massages start at \$6 for 10 minutes. Baldwin Enterprises has a kiosk at NorthTown Mall and plans on opening another at the Silver Lake Mall.

Unkman, MD
Bianchi, MD
2002-12-0019
Place on Pile



As Seen on
OPRAH
& NBC's
TODAY
SHOW

UNWANTED HAIR GONE!

Imagine a LASER so FAST, AFFORDABLE and PERMANENT -Enough to eliminate, SHAVING, PLUCKING, WAXING, ELECTROLYSIS and RAZOR BUMPS FOREVER!!!

Bikini Line.....	\$149	Back.....	\$229
Neck.....	\$149	Chin.....	\$129
Underarms.....	\$159	Upper Legs.....	\$229
Shoulders.....	\$179	Lower Legs.....	\$209
Lip.....	\$119	Eye Brows.....	\$129



Spokane Valley Mall
1-888-552-7859

000001

NOTICE

WAC 246-15-030, procedures for filing, investigation, and resolution of whistleblower complaints.

(1)(b) Instructs that staff will affix a permanent cover to the letter of complaint or other form of notice in the complaint file, noting the statutory citation concerning protecting the identity of the complainant.

(3)(c) Ensure upon case closure, that the permanent cover affixed in subsection (1)(c) of this section will remain.

RCW 43.70 provides that the identity of a whistleblower who complains in good faith to the Department of health about the improper quality of care by a health care provider as defined in RCW 43.72.010 **shall remain confidential**.

Pursuant to the above RCW and WAC it is staff's duty to see that the complainant's name or any information which may identify the complainant is not disclosed.

NOTICE

000002

12-10-02

To: Intake Coordinator
From: G. Heye
Subject: New complaint

I received a phone call today about a hair removal business in the Spokane Valley Mall. The business is called "DEVA" and it offers photorejuvenation through the use of a pulsed light unit called "Aurora", manufactured by Syneron. The store advertises hair removal, treatment of vascular lesions such as leg veins, and treatment of superficial pigmentation problems. The personnel doing the treatments are reportedly not medically licensed in any way but may have been trained by the company that manufactures the machine. There may be some medical supervision but no doctor is on sight.

Please open a case under "Unknown MD".

Thank you.

gh

000003

Nuvo

Laser Skin Enhancement Clinics

Welcome to *Nuvo*, America's leading skin enhancement and hair removal clinics! Unwanted hair and problematic skin can now be a thing of the past! Wrinkles, signs of aging, redness, and sun damage can now be treated quickly, comfortably, effectively and safely with no down time. In this rapidly growing industry you may be wondering how to select the right clinic. If you are interested in cutting edge technology delivered in an energetic style where the customer's satisfaction is our number one priority, then you have found it.

Nuvo has become a trusted name in the laser skin enhancement and hair removal industry, with our highly trained staff of registered nurses having performed over 40,000 successful treatments. Through our experience in the industry, *Nuvo* has developed our exclusive systems that allow us to treat all skin types, including naturally dark and tanned skin. *Nuvo* is also able to treat all hair colors, including blonde and gray or white hair.

At *Nuvo*, we incorporate aggressive treatment protocols with various energy levels, pulse durations and treatment intervals. Coupling our experience with access to a variety of technology and laser systems, we can effectively target each individual's specific needs.

Your time is important to us. Treatments can be done at your convenience, and in record time. Even some of the most problematic conditions can be treated in just minutes. We've been able to reduce treatment times, allowing you to get the results you want, without taking away too much valuable time from your busy schedule.

We realize that comfort and safety is very important to you. At *Nuvo*, we have trained our staff to the highest standards in the industry, allowing us to treat each client virtually pain-free, with patients being able to resume a normal lifestyle within just minutes of treatment. *Nuvo* feels very confident that your experience will be surprisingly comfortable, enjoyable and most importantly, rewarding!

Imagine having hair free, younger looking, smooth skin in just a few treatments.

Find out for yourself!

Call us today and let us exceed your expectations! We look forward to serving you!

The Staff at Nuvo

Nuvo of Spokane
Spokane Valley Mall
14700 East Indiana Street Ste #1092 – Spokane, WA 99216
(509) 927-9400

Nuva

Common Questions & Concerns For laser hair removal

How does it feel?

Most patients tolerate the treatment very well and report that it is more comfortable than some of the other hair removal methods that they have tried. Patients who do feel discomfort during treatment often report the sensation feels like a rubber band snap ranging from mild to moderate. A warm sunburn feeling can also occur which usually subsides in less than an hour. For people who are extremely sensitive we have a topical anesthetic available to be applied before treatment.

What happens to my skin?

Your skin should not show any sign that you've had treatment for unwanted hair. Temporary side effects such as redness and slight swelling usually disappear within one half hour. The redness in the skin is caused by both the heat of the intense light and by the ice applied immediately following treatment. These side effects are again temporary and disappear quickly after treatment.

Is this permanent?

Yes, it is true. The follicles that have been effectively treated will not be able to produce new hair. It is also true that the follicles that produce your unwanted hair are only vulnerable to the lasers energy when they are actively growing. Therefore, a particular body part will usually require a series of treatments to treat follicles that were once dormant as they become active. This will produce a thinner re-growth of hair after each treatment.

If you have any further questions or to set up your first appointment, please call us at (509)927-9400.

* Help us fit your schedule by calling and booking in advance of when you'd like to start your treatment as we are often booked out 2 weeks or longer.

Pre-Treatment Instructions

* Please do not wax, bleach, tweeze, or use a chemical depilatory 2 weeks prior to and during laser treatment. Shaving is OK.

* Avoid tanning or sun exposure prior to treatment for a minimum of 7 days in treatment area. If sun exposure is unavoidable prior to treatment, apply sun block (minimum SPF 30) in areas to be treated.

* Prior to treatment, the area should be shaved. If you are unable to shave the area that is to be treated, shaving can be performed here normally for a \$25.00 fee.

* Please wear white cotton undergarments as the laser is potentially attracted to dark colors.

* Please notify our office if there has been any changes in your health status, or if you have been prescribed antibiotics or steroids so we can reschedule treatment.

000005

Nuvo

Laser Skin Enhancement Clinics **Botox Information Sheet**

Botox treatments are becoming increasingly popular. *Botox* is a very effective method for reducing wrinkles. *Botox* can be used to smooth wrinkles in the neck and face for a more youthful appearance.

The solution used in these treatments is made from *botulinum A* toxin, a purified protein made from *botulism* bacteria. This solution temporarily paralyzes nerves of the facial muscles so they cannot contract and cause wrinkles in the area being treated. **Botox** paralyzes the nerve by blocking the release of acetylcholine, which is the neurochemical that causes muscles to contract. It takes about 3 months for the nerve to recover and begin to release acetylcholine again.

During your initial consultation, you will have the opportunity to talk with the doctor about the changes you may expect in your appearance. She will explain the procedure and risks and limitations involved and answer any questions you may have.

Botox treatments are brief and simple. The procedure can be done with pre-treatment if requested. The skin can be pre-treated with a topical numbing agent, this takes about 20 minutes to take effect. Once the preparation is complete, very small amounts of *Botox* are strategically injected in different parts of the face. This is accomplished with tiny needles that cause very little pain. Depending on the number of injections, the treatment takes 10 to 20 minutes.

There is some discomfort involved with the injections, but the discomfort is slight. The feeling is similar to a small insect bite, but as soon as the procedure is complete, there is virtually no pain. You can return to work or resume your regular activities. You will be given a Post Care Instruction Sheet.

The results are generally visible within 5 to 10 days. Results vary, the results of an individual treatment last for 3-4 months. The procedure should be repeated and with each new treatment, the results tend to last longer.

You are a good candidate for this procedure if you:

1. want to remove wrinkles in the face or neck
2. are knowledgeable about the procedure
3. are in good physical and psychological health
4. want to improve your appearance
5. are realistic in your expectations

The risks include mild bruising or swelling that may occur at the site of the injection. The treatment may also cause a brief headache. In rare cases, the injections may cause the eyebrow or upper eyelid to droop, but this condition is temporary and corrects itself without treatment within 2 to 3 weeks.

Additional important information:

This procedure can remove or deter wrinkles by preventing the repeated facial expressions that contribute to their formation. While it cannot improve the overall texture of the skin, procedures such as laser skin resurfacing and dermabrasion can be used to accomplish this. *Botox* does not tighten the facial skin, as facelifts and brow lifts can. *Botox* is frequently performed in combination with one or more of these other procedures for the best possible outcome. **Please ask for more information about these additional procedures if you are interested.**

000006

Nuva of Spokane

Reminders and Referrals

** For hair removal treatments remember your hair may not shed for 10-21 days following your treatment.*

** For skin enhancement treatments, although you'll see some immediate changes and improvements, collagen stimulation gradually increases 14-28 days after your treatment. Skin texture and clarity will gradually improve 10-30 days after your treatment. Following a botox treatment you should see improvements within 72 hours, with gradual improvements for up to 30 days.*

** Following a treatment, avoid exposure to the sun for about a week. If you need to be in the sun, you should apply sun block (Nuva for sun SPF 30) in the areas you have treated.*

** Temporary side effects such as blisters are rare, however should a blister occur, apply an antibiotic ointment and notify our office at 509-927-9400.*

** Your follow up treatment should be in the next 4-8 weeks depending on the type of treatment or area treated. We'll be calling you to confirm your appointment 24-48 hrs. in advance.*

** If you have any further questions or concerns, please do not hesitate to call us.*

Thank you

The Staff at Nuva of Spokane

Remember: Refer family and friends for their free treatment.

Name of referral: _____ Referred by: _____

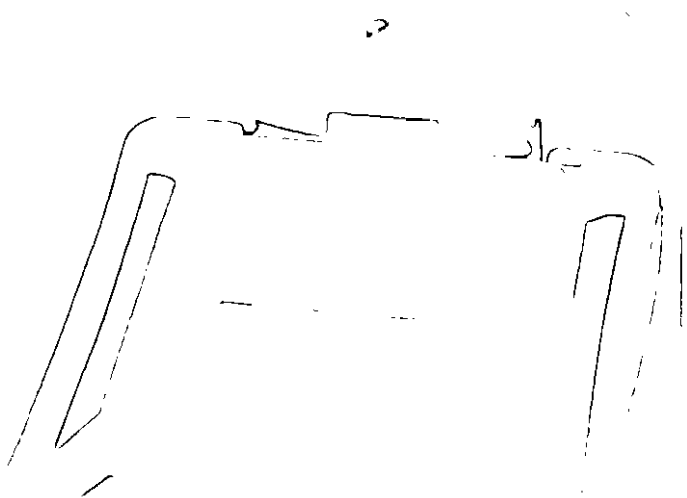
000007

What makes Aurora different?

Aurora is based on a unique technology, called ELOS™, which utilizes the synergy of electrical energy and light to remove hair more gently, more effectively than any other system.

Aurora:

- ☐ Uses less energy, which means more safety (particularly if you have dark skin)
- ☐ Causes fewer, milder side-effects
- ☐ Is more comfortable before and after treatment
- ☐ Removes more hair in fewer treatments



The Aurora hair removal system is provided by:

Syneron Inc.

100 West Beaver Creek Rd. Unit 6
Richmond Hill, Ontario, Canada
L4B 1H2

Tel : (905) 886-9235

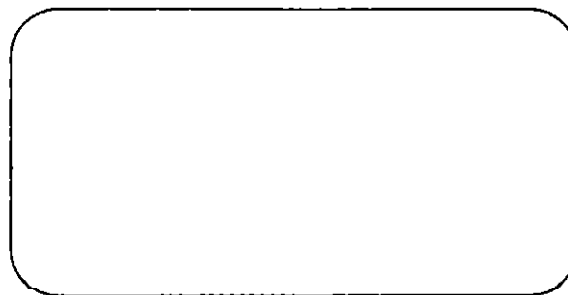
Fax : (905) 886-7046

Toll free: (866) 259-6661

email: gordonp@syneron.com

www.syneron.com

For more information,
contact:



Syneron



Say goodbye to unwanted hair



Gentle

long-lasting
hair removal
for men & women

Syneron

Safe, effective hair removal is now within your reach



Removing unwanted hair from your face or body is now easier and more comfortable than ever before. Instead of shaving, tweezing, or waxing, and instead of going through painful electrolysis or laser treatments, you can now enjoy comfortable, long-term hair removal.

The Aurora™ hair removal system utilizes advanced technologies based on proven science. It treats unwanted hair safely, quickly and very effectively, eliminating the hair at root level and severely reducing re-growth.

Please talk to your doctor to answer any questions and to discuss your hair removal goals. Your doctor is best qualified to assess your suitability for this treatment.

Aurora Hair Removal System

How does Aurora work?

Aurora is a faster, gentler way to remove unwanted hair, with long-term results. It applies precisely controlled pulses of energy (electrical and light, with cooling), reaching into the hair follicles that lie beneath the skin. The energy heats the hair, right down to the bottom of the root, destroying it without damaging surrounding tissue or skin.

What does it feel like?

Each pulse, which lasts less than one second, produces a slight tingling feeling. In particularly sensitive areas, such as the upper lip, it may feel like a quick, light pinch.

Is it suitable for everyone?

Aurora enables your doctor to customize the treatment to exactly match your hair and skin color and type. As long as there is some color in your hair (even blond hair has enough color), then Aurora will be effective.

What about side effects?

The energies used by Aurora (electrical and light) are both commonly used in a range of medical and cosmetic procedures and have proven to be safe. Most people experience no side effects at all, though a few exhibit some short-term local reddening of the surrounding skin. You can return to your regular activities immediately after treatment, although it is advisable to keep the skin protected from exposure to direct sunlight for a short period of time.

How many treatments will I need?

Similar to other technologies, Aurora destroys hairs that are in the active growth phase; so repeat treatments will be needed to target hair that was not affected at the time of the previous treatments. The number of treatments you will need depends on your hair and skin color and type, and the part of your face or body treated. Your doctor can advise you about how long it will take to reach your hair removal goals. (Usually, four to six treatments are required.)

What results can I expect?

Aurora has been proven to be effective for long-term hair reduction with each individual treatment. At the end of the treatment program you can expect your skin to remain smooth.

What makes Aurora different?

Aurora is based on a unique technology, called ELOS™, which utilizes the synergy of electrical energy and light to improve the appearance of your skin more gently, more effectively than any other system.

Aurora:

- ☐ Uses less energy, which means more safety (particularly if you have dark skin)
- ☐ Causes fewer, milder side-effects
- ☐ Is more comfortable before and after treatment
- ☐ Treats a greater range of lesions

The Aurora skin rejuvenation system is provided by:

Syneron Inc.

100 West Beaver Creek Rd. Unit 6
Richmond Hill, Ontario, Canada
L4B 1H2

Tel : (905) 886-9235

Fax : (905) 886-7046

Toll free: (866) 259-6661

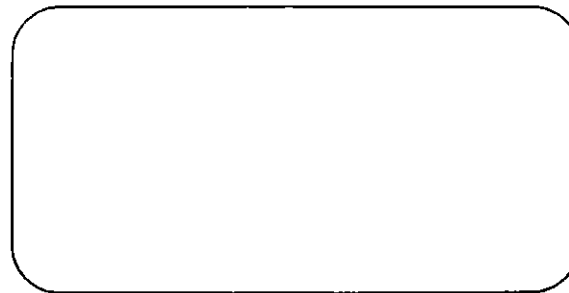
email: gordonp@syneron.com

www.syneron.com



Skin Rejuvenation

**For more information,
contact:**



Enjoy
a smoother
more youthful
appearance

Syneron

Skin renewal is now safer, gentler and more effective



Removing unattractive lesions is now easier, more comfortable than ever before. Instead of enduring painful procedures that use intense heat, light or laser, you can now enjoy comfortable, long-lasting skin renewal that produces the results you truly want.

The Aurora™ skin rejuvenation system utilizes advanced technologies based on proven science. It uses a unique combination of electrical energy, light and cooling to treat vascular lesions (facial telangiectasias, rosacea, etc.) and superficial pigmented lesions (such as age spots, solar lentigo, and others) safely, quickly and very effectively.

Please talk to your doctor to answer any questions and to discuss your skin renewal goals. Your doctor is best qualified to assess your suitability for this treatment.

Aurora Skin Rejuvenation System

How does Aurora work?

Aurora is a safer, gentler way to smooth and remove many types of facial skin imperfections. It applies precisely controlled pulses of energy (electrical energy and light, combined with cooling), removing a wide variety of vascular lesions and pigmented lesions without damaging surrounding tissue or skin.

What does it feel like?

Each pulse, which lasts less than one second, produces a slight tingling feeling. In particularly sensitive areas it may feel like a quick, light pinch.

Is it suitable for everyone?

Aurora can be effective on all types of skin and on a wide variety of lesions and skin irregularities. Your doctor will customize the treatment to exactly match your skin type and treatment goal.

What about side effects?

The energies used by Aurora (electrical and light) are both commonly used in a range of medical and cosmetic procedures and have been proven to be safe. Most people experience no side effects at all, though a few exhibit some short-term local reddening of the surrounding skin. You can usually return to your regular activities immediately after treatment, although it is advisable to keep the skin protected from direct sunlight for a short period of time.

How many treatments will I need?

Excellent results can be achieved in a single session. If multiple types of lesions are to be treated, several treatments, spaced three to four weeks apart, may be required. Your doctor can advise you about how long it will take to reach your skin renewal goals.

What results can I expect?

Aurora has been proven to permanently remove vascular lesions and superficial pigmented lesions. At the end of the treatment program you can expect your skin to be smoother and clearer.

We believe that everyone should have the opportunity to look in the mirror and feel good about what they see!

Our staff of clinical skin care professionals believe that preventative intervention through well-formulated treatment is very important in correcting and maintaining healthy and beautiful skin.

Our carefully selected services are all performed by a dedicated and experienced staff, ready to partner with you to customize an all around beauty and skin fitness program for your specific needs. We use modern technology and the most advanced cosmetic treatments available to bring your skin back to its original youthful state.

We have the latest and most advanced FDA approved permanent technology on the market. We continually upgrade our systems to offer you the latest that science has to offer. We are able to treat any hair or skin color, safely, quickly and it is painless

We are looking forward to the opportunity to successfully address your hair removal needs.

Services Available To You:

- Laser Hair Removal
- Vein Removal
- PhotoFacial-RF
- Skin Rejuvenation
- Microdermabrasion
- Collagen Remodeling
- Chemical Peels
- IPL-RF Hair Removal
- Botox
- Sclerotherapy
- Collagen Injections
- Acne Scars
- Stretch Marks
- Active Acne Removal
- Anti-Aging
- Anti-Wrinkles
- Skin Lightening

***Our Consultations Are Free...
The Results Are Priceless!***

**NUVO OF SPOKANE
SPOKANE VALLEY MALL
14700 E INDIANA AVE,
SPOKANE, WA 99216
(509) 927-9400
www.nuvointernational.com**



**Photo
Rejuvenation**

**Laser
Hair
Removal**

**Laser
Leg Vein
Therapy**

PhotoRejuvenation-RF



Before

After



Before

After

Achieving a more youthful appearance is now simpler and more effective than ever before. Your treatment is always

performed using the most current technology available. You are assured a complete solution to the challenges of skin renewal. We are able to treat a full array of vascular lesions (such as facial telangiectasias and rosacea), superficial pigmented lesions (such as age spots, solar lentigo, etc.) and skin texture imperfections, providing exceptional results with maximum patient comfort. Treatment also improves mild acne scars, reduces large pores, corrects dark circles around the eyes and reduces fine lines. Treatments are especially effective for improving the appearance of the neck, chest, and hands. This exciting solution involves no "down time." You can resume normal activities immediately. Your treatment will be performed using the latest technology in intense pulse light PhotoRejuvenation. This recent breakthrough involves combining intense pulse light with radio frequency energy. The result is a more effective treatment, performed in less time, with minimal discomfort. Imagine your skin being easily and safely transformed into a younger, healthy, vibrant looking appearance. Our new IPL-RF PhotoRejuvenation treatment is the answer for renewing your skin through technology.

Permanent Hair Removal



Before

After

Finally, there is a better way to be free of unwanted hair. First there was electrolysis; effective, but slow, painful, and expensive. Then, the first lasers came to market. They were quicker and less painful, but not permanent. Since then great improvements have been made in laser technology, but there are still limitations in treating dark skin and light colored hair. Now, because of an exciting new breakthrough in laser technology, we offer the latest FDA approved device for permanent hair removal. We can now effectively treat any skin color and hair color, with no negative side effects. Even grey hair and dark skin tones can enjoy the benefits of permanent hair removal. All of this without the use of messy and ineffective dyeing methods on grey hair, or without the burning and blistering on dark skin. The treatment uses a breakthrough in hair removal technology. By combining intense pulse light with radio frequency energy, hair follicles are permanently disabled, without regard to hair color or skin tone. We are proud to be the leader in hair removal technology and have the solution for even the most difficult hair removal needs. Everyone can now enjoy the benefits of permanent hair removal. Our professional staff of experienced technicians look forward to the opportunity of successfully addressing any hair removal need.

Laser Leg Vein Therapy



Before

After

This exciting treatment is extremely safe and effective on leg veins, as well as veins visible on the face and chest--just about anywhere! These non-invasive treatments are increasingly popular because there are very few side effects, with amazing results of beautiful, smooth, vein-free skin. The number of treatments necessary to resolve your vein problem depends on the size of the vein and your body's ability to heal. During your consultation an approximate number of treatments will be recommended. Our laser therapy allows customized treatment of virtually every small vein disorder, including deep veins and veins that do not respond to other treatment methods. The beauty of this treatment is that there is no down time involved. You can resume regular activities immediately. Our treatment process implements state of the art longwave length laser technology to quickly and safely remove unsightly veins.

Call today to schedule your consultation and find out how these procedures can benefit you!



Applying the science of beauty

THE NUVO LASER SKIN Clinic opened up in the Spokane Valley Mall only a short while ago, but already they have a devoted clientele. "This is the cutting edge way of improving the appearance of your skin and permanently getting rid of unwanted hair," says Jeff Gelnette, Nuvo's owner and manager.

Nuvo's popularity springs mainly from the availability and reliability of advanced technologies. Prior to this new science, those interested in hair removal had few choices, none of which could guarantee permanency. Waxing, acidic creams, and electrolysis can be both painful and unpredictable. And as for erasing the signs of aging, the only viable choice was to pay a costly visit to the plastic surgeon's office.

The Aurora Skin Rejuvenation System is a safer, gentler way to smooth and remove many types of facial skin imperfections. It applies precisely controlled pulses of energy (electrical energy and light, combined with cooling) to remove a wide variety of vascular lesions and pigmented lesions, as well as age spots and solar lentigo, without damaging surrounding tissue or skin.

"We have a number of patients who suffer from rosacea," says Gelnette. "The results are very positive. And it works on scars and stretch marks. We start with a microdermabrasion, which is a mild exfoliation process that shoots a fine aluminum crystal into the skin and immediately vacuums it out. Besides preparing the

skin for the photo-rejuvenation process, this also causes the skin to produce more collagen, which reduces the appearance of wrinkles."

Kim Barker had stretch marks smoothed away at the Nuvo valley clinic. "It really worked. They are completely invisible, and mine were terribly pronounced," says Barker. "I'm going to have some other stretch marks from another spot on my body treated as soon as possible. It is really amazing, and I'm very happy with the results." Barker was also surprised at how she was able to resume normal activity immediately afterward.

"It's such a neat thing to be able to help people," Gelnette enthuses. "We had a woman come in here recently who had a very low hairline. She had been troubled by it her entire life. We treated her just once, and she came back a few weeks later to show us how the hair hadn't grown back; she was practically crying with joy. Now, that's admittedly rare; it usually takes three or more treatments to make sure that all of the hair follicles have been treated because hair goes through growth phases. Another man came in because he felt it was his last option. He was too embarrassed to even take off his shirt or go swimming because of how much hair he had on his back. It's just great seeing people become more comfortable with themselves."

Having been a minister for over 20 years at the Coeur d'Alene Bible Church, and an attorney before that in Pennsylvania, Gelnette isn't just blowing hot air. Making people feel better and helping them solve their problems is something that he's been called to do. "You know, when I first looked into opening this Nuvo clinic, I thought it was all about vanity. But people are really changed. Some bodily imperfections can be very troubling for people. This is about feeling better, not just looking better."

The Nuvo Laser Skin Clinic in the valley also offers Botox injections. "Our medical director, Dr. Elizabeth Bianchi M.D., specializes in facial aesthetics. She handles all the more invasive procedures," says Gelnette.

Pay Nuvo a visit and see what they can do for you.

000008

Nuvo of Spokane is located in the Spokane Valley Mall at 14700 E. Indian St., space 32, next to the Bon Marché, and can be reached at (509) 927-9400.



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Health Professions Quality Assurance Division
Investigation/Legal Unit
Freeway Plaza Building, Suite 313
West 1500 Fourth Avenue
Spokane, WA 99204

April 25, 2003

Attn: Jeffrey A Gelnette, Manager
Nuvo Laser Skin Clinics
Spokane Valley Mall
14700 E. Indiana, Suite 1092
Spokane, WA 99216

Re File No.:2002-12-0019MD

Dear Dr. Jeff:

The Washington State Medical Quality Assurance Commission has received a confidential inquiry regarding your operation – Nuvo Laser Skin Clinics – in the Spokane Valley Mall.

The Washington State Medical Quality Assurance Commission is the entity within State government with legislated authority and responsibility to assure the delivery of safe medical care. Under the provisions of RCW 18.130.050, the Washington State Medical Quality Assurance Commission is empowered to investigate all allegations and complaints to determine whether such allegations are substantiated and to take disciplinary or corrective action, if warranted.

Please be advised that this is a preliminary investigation only and that no charges have been issued in connection with this investigation.

The Health Care Information Act, RCW 70.02.050 (2)(a), requires that a health care provider disclose health care information about a patient without patient authorization when that information is needed to determine compliance with state licensure rules or laws

Under provisions of the above laws you are requested to provide:

- 1) A copy of your business license; Names, addresses & telephone numbers of current employees; A list of licensed and/or certified therapists as well as copies of their licenses and /or certifications including Medical Director. Job descriptions of current positions.



Apr. 25, 2003
Page 2

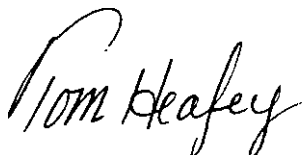
- 2) Identification of equipment used (i.e. Aurora); Whether licensed by FDA, if so, their numbers; Where purchased; by whom. An explanation of how they are used.
- 3) Access to appointment book and a copy of certain patient records that are randomly chosen by the investigator.
- 4) A list of medications used, by who and what for. Other than the physician, who else administers medications? Are topical anesthetics used and how?

Please send copies of the records within fourteen (14) days after receipt of this letter.
Copies are to be sent to:

Tom Heafey, Health Care Investigator III
Department of Health
Medical Investigations Unit
Freeway Plaza Building, Suite 313
1500 West Fourth Avenue
Spokane, WA 99204

If you have any questions concerning this request please contact me at (509) 458-3642. Thank you for your anticipated cooperation.

Respectfully,



Tom Heafey, Senior Investigator



May 8, 2003

State of Washington
Department of Health
Health Professions Quality Assurance Division
Freeway Plaza Building, Suite 313
West 1500 Fourth Ave.
Spokane, WA 99204

File No. 2002-12-0019MD

Dear Mr. Heafey:

Pursuant to your letter dated April 25, 2003, please find enclosed the following:

1. A copy of our business license and UBI certificate.
2. A list of our current employees, including their addresses and telephone numbers.
3. A list of our licensed and/or certified employees' credentials. This includes our physician, estheticians and laser technicians.
4. A list of brief job descriptions of our employees.

Nuvo of Spokane has two lasers that are used for hair removal and vascular/pigmented lesions procedures. They are both the same model machine. The brand name of the machines is Aurora. They are made and marketed by Syneron, Inc. The address for Syneron is 100 West Beaver Creek Rd., Unit 6, Richmond Hill, Ontario, Canada L4B 1H2. Their telephone number is 866-259-6661 (toll free). The Aurora was approved by the FDA for hair removal on July 10, 2002 (K021149) and for superficial, benign vascular and pigmented lesions on October 10, 2002 (K022266). They are used for their intended purposes.

Nuvo of Spokane also has a microdermabrasion machine. It was manufactured by General Project in Florence, Italy. It is a GPI model, serial number 20149, 110 volts and 550 watts. It is used for mild exfoliation of the skin. I do not know if this has FDA approval or not.

Nuvo of Spokane has recently installed a spray on tanning booth. It is manufactured by Wolff Tanning Systems. It was purchased from ETS, Inc. in Indiana. I called ETS and they said that it did not require FDA approval. It is used to give sunless, UV free tanning as an alternative to the conventional tanning methods.

You are free to access our appointment books and patient records. We are giving you permission to do this pursuant to RCW 70.02.050 and HIPAA, 45 C.F.R. Section 164.512(d)(1).

The only medications that are used at Nuvo of Spokane are Botox® Cosmetic, collagen injections, the solution used in sclerotherapy and topical anesthetic. These are used only by Dr. Elizabeth Bianchi. Topical anesthetic is only used when Dr. Bianchi examines the client and gives them a prescription for them to purchase. It is never administered by anyone at Nuvo of Spokane. We have been very careful never to have anyone other than Dr. Bianchi or the client's personal physician recommend any medications.

I trust that this satisfies that requirements of your above described request letter. Should anything further be necessary, do not hesitate to contact me.

Very truly yours,



Jeffrey A. Gelnette
Manager

JAG/pc
enclosures

CERTIFICATE OF COVERAGE



Insurance Services Division
Employer Services

Department of Labor & Industries
PO Box 44144
Olympia WA 98504-4144
www.LNI.wa.gov

EMPLOYER: This official certificate of industrial insurance coverage is in lieu of a policy. It remains in effect until your account is officially closed. There is no limitation of benefits. You are required by law to post both this certificate and copies of the posters listed below. You will soon be receiving 1 copy of each. If you require additional copies, call Labor and Industries at 360-902-4817.

- Job Safety and Health Protection (available in Spanish)
- Your Rights as a Worker/Family Care
- Notice to Employees

WORKER: The employer named below is an insured policyholder with the Washington State Industrial Insurance Trust Fund.

UBI* 602 232 573 Policy Effective Date
09/30/02

Location

NUVO
SPOKANE VALLEY MALL
14700 E INDIANA AVE SPACE 1092
SPOKANE WA 99216

Employer

SKIN NUVO OF SPOKANE LLC
NUVO
SPOKANE VALLEY MALL
14700 E INDIANA AVE SPACE 1092
SPOKANE WA 99216

*Your Unified Business Identifier is the only number you need to discuss your business account with the Washington state departments of Revenue, Licensing, Employment Security, Labor and Industries and the Office of the Secretary of State. Other state licenses or registrations may be required for proper licensing of your business.

F211-141-000-18/02



STATE OF
WASHINGTON

MASTER LICENSE SERVICE REGISTRATIONS AND LICENSES

UNIFIED BUSINESS ID #: 602 232 573
BUSINESS ID #: 001
LOCATION: 0001

ORGANIZATION TYPE
DOMESTIC LIMITED LIABILITY COMPANY

SKIN NUVO OF SPOKANE LLC
NUVO
SPOKANE VALLEY MALL
14700 E INDIANA AVE SPACE 1092
SPOKANE WA 99216

TAX REGISTRATION
UNEMPLOYMENT INSURANCE

INDUSTRIAL INSURANCE

REGISTERED TRADE NAMES:
NUVO

The above entity has been issued the business registrations or licenses listed
DEPARTMENT OF LICENSING, BUSINESS & PROFESSIONS DIVISION,
P.O. BOX 9034 OLYMPIA, WA 98507-9034 (360) 664-1400

Paul Stephens
Director, Department of Licensing

Nuvo Employees

1. Kim Barker – 489-2581
5612 N. Post
Spokane, WA 99205
2. Dr. Elizabeth Bianchi – 995-0368
E. 10808 46th Ave.
Spokane, WA 99206
3. Jenae Denlinger – 533-9330; cell – 599-5272
1917 S. Bogart Ct.
Spokane, WA 99223
4. Amy Gelnette – 218-1668; work -924-9944
11312 E. Mission Apt. 16
Spokane, WA 99206
5. Jeffrey/Sherri Gelnette – 208-687-0007; cell – 509-869-8828
~~835 Logan Street~~ *15620 N. McCartney St.*
Rathdrum, ID 83858
6. Cindy Holstine – 218-9618
1117 W. Paradise Rd.
Spokane, WA 99224
7. Stephanie Johnson – 208-704-6496
4301 N. Ramsey Rd. #F2-26
Couer d'Alene, ID 83815
8. Debra Powell – 208-777-4046
201 E. 1st Ave.
Post Falls, ID 83854
9. Anna Seier – 443-6674; cell – 216-1026
2525 E. 53rd #B-109
Spokane, WA 99223
10. Kimberly Stoker – 869-3960
1719 N. Harmony Lane
Greenacres, WA 99016
11. Robyn Stone – 928-2903; wk – 927-3272
1722 N. Raymond Rd.
Spokane, WA 99206
12. Theresa Wyer – 292-8009; cell – 868-9574
P.O. Box 490
Chattaroy, WA 99003

0095- X804

SKIN NUVO OF SPOKANE LLC

PAGE 1

		HOURS		EARNINGS				WITHHOLDING TAXES				VOLUNTARY DEDUCTIONS & OTHER ADJUSTMENTS				
EMP NBR WCOMP CLASS	EMPLOYEE NAME	T Y P E	RATE	REG	OT	REGULAR	OT	1 COMMI SSION 2 OE II	TOTAL EARNINGS	SOC SEC MED.	FEDERAL	STATE	LOCAL DBL/SUI	2 DRAW	NET PAY	CHK NBR
****	000100 STAFF															
000003 6501	BARKER KIMBERLY M		10000	7125												
000012 6501	BIANCHI ELIZABETH A			8000												
000006 6501	DENLINGER JENAE E		15000	7600												
000009 6501	GELNETTE AMY L		15000	3550												
000005 6501	GELNETTE JEFFREY A			8000												
000008 6501	GELNETTE SHERRI L		10000	1300												
000010 6501	JOHNSON STEPHANIE M		7500	1800												
000002 6501	POWELL DEBRA L		12000	5650												
000007 6501	SEIER ANNA		10000	7550												
000004 6501	STOKER KIMBERLY K		15000	6500												
000011 6501	STONE ROBYN K		15000	1375												
000001 6501	WYER THERESA S		12000	6825												
	Holstine, Cindy															
000012 TOTALS																
	EARNINGS TYPE			HOURS												
	REGULAR			65275												
	OVERTIME			00												
	VACATION	VA		00												
	HOLIDAY	HO		00												
	SICK/QUALIFIED	QS		00												
	SICK/NON-QUAL	NS		00												
	MISCELLANEOUS	MI		00												

0095- X804

SKIN NUVO OF SPOKANE LLC

Certificate of Training

the
FotoFacial  **RF**™
ELOS™ TECHNOLOGY

A SYNERGY OF PULSED OPTICAL LIGHT AND RADIOFREQUENCY ENERGY

Elizabeth Bianchi, MD

Completed the Advanced Certification Course in the
FotoFacial RF®, ELOS™ technology, Laxity Vector Therapy and Wrinklelite® procedures.


R. Stephen Mulholland, M.D.

SpaMedica USA


Patrick Bitter, Jr., M.D.

SpaMedica USA



Elizabeth A. Bianchi, MD

has satisfactorily complied with and completed the statutory requirements set forth in title 18.71 Revised Code of Washington to engage in the practice of

Medicine and Surgery

and is hereby authorized, empowered, and granted the right to engage in that practice within the State of Washington subject to the state laws.

*Given under the hand and seal of the director
this 14th Day of July 1997*



Bonnie L. King

BONNIE L. KING, ACTING DIRECTOR, HEALTH PROFESSIONS QUALITY ASSURANCE

MEDICAL QUALITY ASSURANCE COMMISSION

JULIAN ANSELL, MD, CHAIR

No. 35207

Perfect Skin

Laser Center

This Certifies That

Elizabeth Bianchi, MD

Has successfully completed a comprehensive training course on


BOTOX

**In Witness Whereof, we have hereunto put our hands and affixed the Official Seal of
Certification at Boise, Idaho, this day the 6th of November 2002 AD.**



Medical Director





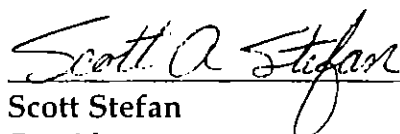
Administrator

Verifies that
Elizabeth Bianchi, MD
Has successfully completed
***Advanced FotoFacial® and
Multi-Application Certification Workshop***
on
November 23, 2002
at
**Hyatt Regency
Burlingame, CA**


Innovative Surgical Concepts, Inc. is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Innovative Surgical Concepts, Inc. designates this continuing medical education activity for a maximum of 11.5 hours in Category 1 credit toward the Physician's Recognition Award of the American Medical Association. Each physician should claim only those hours of credit that he/she actually spent in the educational activity

Provided by: Innovative Surgical Concepts, Inc.
6303 Schofield Avenue
Schofield, WI 54476



Scott Stefan
President



J. Garry Sack, MD, FACS
Education Advisory Council

000019

STATE OF WASHINGTON

HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION

THIS CERTIFIES THAT THE PERSON OR ESTABLISHMENT NAMED HEREON IS AUTHORIZED AS PROVIDED BY LAW AS A

PHYSICIAN AND SURGEON

ACTIVE

BIANCHI, ELIZABETH A.
E 10808 46TH
SPOKANE, WA 99206

Jyc Seluy
SECRETARY

NUMBER		DATE ISSUED	EXPIRATION DATE
025209	MD00035207	07-14-97	07-14-03

Nuvo of Spokane

LASER SKIN CLINIC



STATE OF WASHINGTON

DEPARTMENT OF LICENSING – BUSINESS AND PROFESSIONS DIVISION
THIS CERTIFIES THAT THE PERSON NAMED HEREON IS AUTHORIZED, AS PROVIDED BY LAW, AS A

MANICURIST ESTHETICIAN

GELNETTE, AMY LEIGH
835 LOGAN ST
RATHDRUM ID 83858-9192


DIRECTOR

Reference	Cert/Lic Number	Issued Date	Expiration Date
20916	82869	02-11-03	09-26-03

Laser Hair Removal & Skin Rejuvenation

Presented by

Syneron

This is to certify that

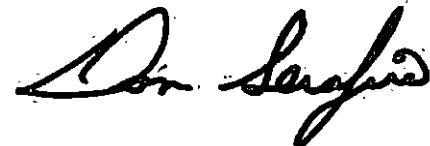
Amy Gelnette

has completed device training for AURORA DSR™
Laser to perform Hair Epilation and Skin Rejuvenation



Joyce Connors, RN
Clinical In-Service Specialist

October 27th, 2002
Date



Dom Serafino
President

STATE OF WASHINGTON

DEPARTMENT OF LICENSING – BUSINESS AND PROFESSIONS DIVISION
THIS CERTIFIES THAT THE PERSON NAMED HEREON IS AUTHORIZED, AS PROVIDED BY LAW, AS A

COSMETOLOGIST ESTHETICIAN

JOHNSON,STEPHANIE MARIE



Led Stephens
DIRECTOR

Reference	Cert/Lic Number	Issued Date	Expiration Date
20905	9487	03-21-97	03-21-05

STATE OF WASHINGTON

HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION

THIS CERTIFIES THAT THE PERSON OR ESTABLISHMENT NAMED HEREON IS AUTHORIZED AS PROVIDED BY LAW AS A

PHARMACY TECHNICIAN

ACTIVE

**STOKER, KIMBERLY K.
1719 N HARMONY LN
GREENACRES WA 99016**

[Signature]
SECRETARY

NUMBER	DATE ISSUED	EXPIRATION DATE
VA00042969	06-27-00	04-15-04

Laser Hair Removal & Skin Rejuvenation

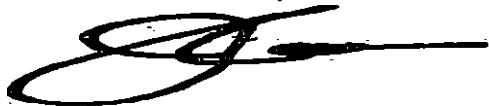
Presented by

Syneron

This is to certify that

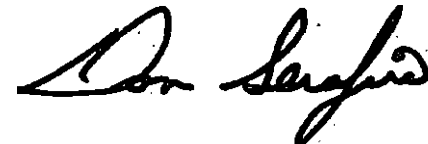
Kimberly Stoker

**has completed device training for AURORA DSR™
Laser to perform Hair Epilation and Skin Rejuvenation**



**Joyce Connors, RN
Clinical In-Service Specialist**

**October 27th, 2002
Date**



**Dom Serafino
President**

000025

STATE OF WASHINGTON		
COSMETOLOGIST		
HOLSTINE, CINDY L.		
1117 W PARADISE RD		
SPOKANE WA 99224-9642		
		DIRECTOR <i>[Signature]</i>
REFERENCE	CERT/ LIC NUMBER	EXPIRATION DATE
20905	24065	02-24-04

Laser Hair Removal & Skin Rejuvenation

Presented by

Syneron

This is to certify that

Jenae Denlinger

**has completed device training for AURORA DSR™
Laser to perform Hair Epilation and Skin Rejuvenation**



**Joyce Connors, RN
Clinical In-Service Specialist**

**October 27th, 2002
Date**



**Dom Serafino
President**



Certificate of Completion

This certifies that

Jenae Denlinger

Has completed training with

Nuvo

"Laser Skin Enhancement Clinics"

*And is fully certified by
Nuvo as a laser technician.*

Certified By: Marilyn Gelnette *Marilyn Gelnette*
Technical Training Specialist

Verifies that

Jenae Denlinger, Technician

Has attended and successfully completed

***Advanced FotoFacial® and
Multi-Application Certification Workshop***

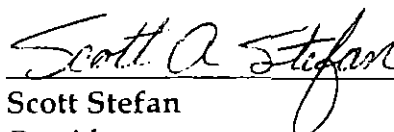
on

November 23, 2002

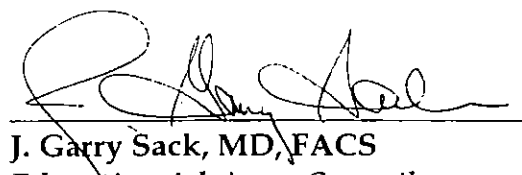
at

**Hyatt Regency
Burlingame, CA**


Provided by: Innovative Surgical Concepts, Inc.
6303 Schofield Avenue
Schofield, WI 54476



Scott Stefan
President



J. Garry Sack, MD, FACS
Education Advisory Council

STATE OF WA							
DEPARTMENT OF LICENSING - BUSIN							
THIS CERTIFIES THAT THE PERSON NAMED HEREON							
OPERATOR							
MANICURE ESTHETICS							
STONE,ROBYN KRISANN							
 DIRECTOR	<table><tr><td>Reference</td><td>N</td><td>Expiration Date</td></tr><tr><td>20905</td><td>ST-ON-ER-K341NP</td><td>07-19-96</td></tr></table>	Reference	N	Expiration Date	20905	ST-ON-ER-K341NP	07-19-96
Reference	N	Expiration Date					
20905	ST-ON-ER-K341NP	07-19-96					



000030

Spokane Community College

Spokane, Washington

This is to certify that

Robyn Krisann Stone

has successfully completed the requirements for

Esthetician

In testimony whereof we have subscribed our names and caused the seal
of the College Board of Trustees to be affixed

Given this twenty-second day of March, two thousand.

Ronald H. LaRayette
President of College



Allen C. Malone
Chair, Board of Trustees

Spokane Community College

Spokane, Washington

This is to certify that

Robyn Krisann Jacobson

has successfully completed the requirements for

Dental Assisting

In testimony whereof we have subscribed our names and caused the seal
of the College Board of Trustees to be affixed

Given this twelfth day of June, nineteen hundred eighty-seven.

Donald E. Bush

President of College



Girard Clark

President of the College Board of Trustees

000032

May 9, 2002

Nuvo of Spokane Employee Job Descriptions

Receptionists: The receptionists answer the telephone, schedule appointments and send correspondence of various types. They also respond to inquiries from people who walk in or clients with questions.

Treatment Specialists: Treatment specialists meet with clients and do evaluations on them. They describe the physiology of hair, the physics of the equipment and they give a good faith estimate of what it would take to accomplish the desired goals (e.g. hair removal). They also explain all the costs involved in the procedures. They are customer service oriented and insure that the clients are satisfied with the procedures.

Laser Technicians: Laser technicians perform the various procedures using the Aurora laser and the microdermabrator.

Medical Director: The Medical Director is a licensed physician in the State of Washington. Her duties include, but are not limited to, the general supervision of laser procedures for hair removal and photo rejuvenation, microdermabrasion procedures and the response to any medical questions that arise in the day to day operation of Nuvo of Spokane. She meets with clients and prescribes a topical anesthetic if it is necessary. She personally treats clients on Botox® Cosmetic treatments, sclerotherapy treatments and collagen injections. She is on call seven days each week.

Manager: The manager insures that the entire operation of the center is handled in a proper manner. He handles payroll, bill-paying and general support of all other employees.

000033



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
*Health Professions Quality Assurance Division
Investigation/Legal Unit
Freeway Plaza Building, Suite 313
West 1500 Fourth Avenue
Spokane, WA 99204*

May 02, 2003

Elizabeth Bianchi, MD
123 E. Indiana
Spokane, WA 99207

CONFIDENTIAL

Re: Our file no. #2002-12-0019MD

Dear Dr. Bianchi:

The Washington State Medical Quality Assurance Commission received an inquiry regarding **Nuvo** operating in the Spokane Valley Mall.

The Medical Quality Assurance Commission is the agency within the State government with legislated authority and responsibility to assure the delivery of safe medical care. Under the provision of RCW 18.130.050, the Commission is empowered to investigate all allegations and complaints to determine whether such allegations are substantiated and to take disciplinary or corrective action if warranted.

Under provision of RCW 18.130.180 and WAC 246-919-620, a Physician shall cooperate with the Commission by providing a full and complete explanation covering the matter under investigation and shall furnish copies of any papers or documents in his/her possession. The Uniform Health Care Information Act, RCW 70.02.050 (2)(a) requires that a health care provider disclose health care information about a patient without patient authorization when that information is needed to determine compliance with state licensure rules or laws.

Under provisions of the above laws, please provide the following information:

- 1) What does being the "Medical Director for **NUVO**" entail?
- 2) What invasive procedures do you perform and is there a patient record?
- 3) What medications are used by **NUVO** under your supervision, i.e. Lidocaine .5% topical anesthetic.
- 4) How are you able to supervise operations in both Seattle and Spokane Valley?



Dr. Elizabeth Bianchi, MD
May 02, 2003
Page 2

- 5) Please note what training and experience you've had in this field.
- 6) How are staff able to distinguish when their treatment is contraindicated?
- 7) How are you compensated? Stock options and/or pay per annum.
- 8) How many times have you been contacted by telephone ? How many times have you had to physically go to the clinic when called?
- 9) Do you have a written contract? If so, please furnish a copy of the same.

Please be advised that this is a preliminary investigation only. The Medical Quality Assurance Commission has not made a determination as to whether further investigation and/or Commission action is warranted.

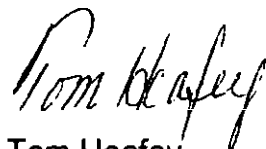
You are free to consult with and engage an attorney at your expense to represent you in this matter prior to making your response. Your response(s) may be used if disciplinary action is deemed necessary. If you wish to have an attorney represent you please have the attorney file a Notice of Appearance at the address below.

Your reply is requested within fourteen (14) days following your receipt of this letter. Please mail your response in care of:

Tom Heafey, HCI III
Department of Health
Medical Investigations Unit
Freeway Plaza Building, Suite 313
1500 West Fourth Avenue
Spokane, WA 99204

If you have any questions, please feel free to contact me (509) 458-3642.

Sincerely,



Tom Heafey,
Senior Investigator

000035

Tom Heafey, HCI III
Department of Health
Medical Investigations Unit
Freeway Plaza Building, Suite 313
1500 West Fourth Ave
Spokane, WA 99204

Dear Mr. Heafey,

The following information is in response to your letter dated May 02, 2003.

1. **What does being the "Medical Director for NUVO entail?**

As medical director for NUVO I am responsible to help ensure client safety through medical review of the *Training and Treatment Protocol Manual*, for the general supervision of procedures done by the staff, including their assessment of dermatological conditions, training and use of the equipment for clinic treatments. As medical director I am available by phone and in person as needed for any medically related questions that might occur for both the Seattle and Spokane locations.

2. **What invasive procedures do you perform/what patient records?**

The only invasive procedures I am performing are Botox® injections and sclerotherapy for small leg veins/telangiectasias. I have enclosed blank copies of the patient chart notes I am using.

3. **What medications are being used?**

Medications used by me at NUVO include Botox Cosmetic®, and 0.2% or 0.3% Sodium Tetradecyl Sulfate solution for sclerotherapy. I occasionally write prescriptions as needed for patients I personally see. On rare occasions I have written prescriptions for 2% lidocaine gel for clients who have difficulty tolerating the hair removal or *Photo Facial* treatments. I always see these clients on days I am in the clinic and discuss their concerns and prescribe the medication as needed.

4. **How you supervise operation in Seattle and Spokane?**

Due to the benign nature of these treatments and their overall safety I am supervising the clinics in Seattle and Spokane by being available by phone or in person virtually 24/7 for any medically related questions that might occur. Any emergent situations would require a 911 call with transfer of clients to the nearest emergency room. For any other medical concerns, a client would be scheduled to see me personally as soon as possible. There is a RN available at the Seattle clinic and I can arrange a flight to Seattle very quickly. (Of note- these procedures are extremely safe and no clients have ever suffered any serious ill effects in the Seattle or Spokane clinics.) I also routinely provide services at the Spokane clinic and travel to Seattle at least monthly to communicate with staff and management regarding any medically related topics. I have also developed a relationship with a local dermatologist who will assist me with any questions or referrals I might have.

5. **Note experience you've had in this field.**

My experience starts with Medical School where I engaged in elective rotations in Plastics and Dermatology. I am a family practice physician trained in a wide range of medical treatments, including basic dermatology procedures. Since my

RT. ST.
Pg-36-37

employment with NUVO I have taken post graduate training in *FotoFacial* (IPL) technology, an intensive workshops for hands-on Botox® injections and sclerotherapy with Dr Ivyl Wells at Perfect Skin Laser Center in Boise.

I have also attended a 2 day Aesthetics workshop and seminar from the National Procedures Institute, which is a national physician training program for procedures and office surgery. This course's objectives included cosmetic patient evaluation, Botox® and collagen injection, skin resurfacing, lasers and hair removal. I continue to stay current with the cosmetically related dermatology literature. I plan to continue to pursue additional CME training in this area.

Dr Wells is also available for consultation as needed.

6. **How is staff able to distinguish when treatment is contraindicated?**

The staff is well trained in what contraindications exist for these cosmetic procedures. They are outlined in the *Training and Treatment Manual*, and I am available to discuss and/or see any clients who may have a medical condition that requires evaluation. All patients fill out a general medical history and are evaluated prior to any procedure.

7. **How are you compensated?**

I am compensated by salary. I have no stock or ownership in the company.

8. **How may times have you been contacted by phone?**

Again, these services are very safe and clients are given informed consent all questions and expectations are addressed. I rarely get any calls regarding patient concern or injury. I have not had any calls for serious patient injury in either the Seattle or Spokane location. I am available to speak with patients by phone as needed and/or to see them if more evaluation is required prior to, or after a treatment.

9. **Do you have a written contract?**

I do not have a written contract.

Please let me reassure you that client safety is of utmost importance to myself and NUVO. Our goal at the clinics is to provide the *best* and *safest* basic cosmetic services available for our clients.

Please let me know if you need any additional information or have any recommendations. Feel free to contact me at 509-995-0368.

Sincerely,



Elizabeth Bianchi, MD
E 10808 46th Ave
Spokane, WA 99206

NUVO
Brief History and Physical Exam

Name _____

Date _____

Drug or other allergies: _____

Do you see a physician for any chronic medical problems? Yes No

If yes, please explain: _____

Are you currently seeing a dermatologist? _____ What is the diagnosed condition _____

List current medications: _____

Pertinent Medical History:

Prior cosmetic treatments:

Desired treatment results:

Exam:

BP

Pulse

Skin evaluation/type:

Assessment:

Plan:

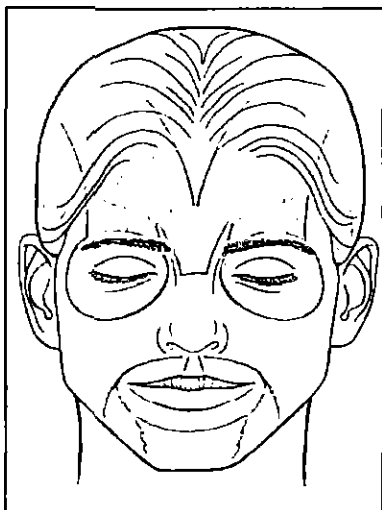
Physician Signature/Date

botoxPE 11/02

BOTOX[®] Cosmetic Injection Site Record

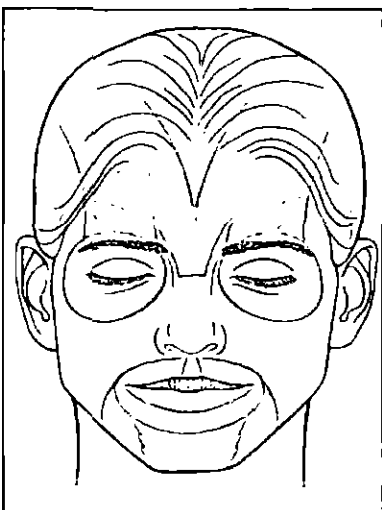
Patient Name: _____
Chart # / Ident.: _____

Notes



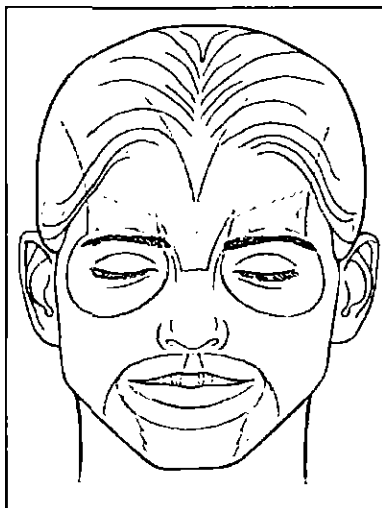
		Area 1	Area 2	Area 3	Area 4
Location					
Botox Lot Number					
Botox Expiration Date					
Treatment Date					
Dilution (cc)					
Units / 0.1 cc					
Total Units / Site					
Site A					
Site B					
Site C					
Site D					
Total Units Used					

Notes



		Area 1	Area 2	Area 3	Area 4
Location					
Botox Lot Number					
Botox Expiration Date					
Treatment Date					
Dilution (cc)					
Units / 0.1 cc					
Total Units / Site					
Site A					
Site B					
Site C					
Site D					
Total Units Used					

Notes



		Area 1	Area 2	Area 3	Area 4
Location					
Botox Lot Number					
Botox Expiration Date					
Treatment Date					
Dilution (cc)					
Units / 0.1 cc					
Total Units / Site					
Site A					
Site B					
Site C					
Site D					
Total Units Used					

000039

Nuvo

Laser Skin Enhancement Clinics
Spokane Valley Mall
14700 E Indiana
Suite 2102
Spokane, WA 99216

Botox Post Care Instructions

1. Exercise the treated muscles every 10-15 minutes for a few hours after treatment.
2. If you get a headache you may take *Tylenol*, unless otherwise advised by your physician.
3. You may try *Arnica* tablets (available at health food stores) if there is any bruising at the site of injections.
4. It will take 5-10 days for the full effect of the *Botox* treatment to take effect.

IF YOU HAVE ANY QUESTIONS OR CONCERNS PLEASE CALL DR BIANCHI
995-0368

Thank you,
DR BIANCHI

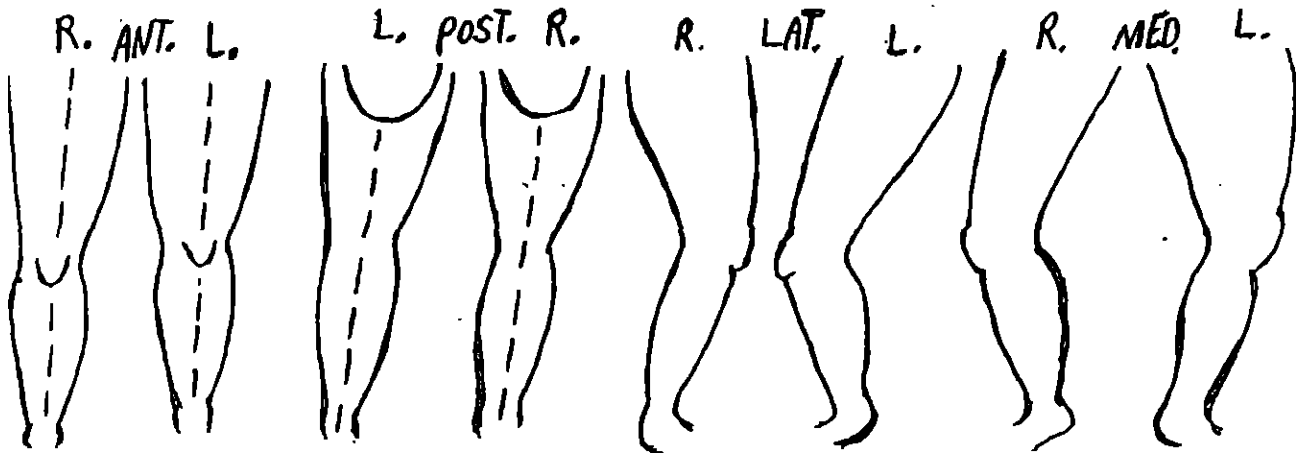
Botox aftercare 11/02

000040

Sclerotherapy Evaluation Sheet

Name _____

Date of Evaluation _____



Recommended Number of Sessions

_____ 60 Minute _____ 45 Minute _____ 30 Minute _____ 15 Minute

Note any concerns: _____

- Answer Questions
- Schedule Appointment
- Purchase/Bring Compression Stockings

Physician Signature _____

000041

Name _____

Sclerotherapy Progress Report

Session # Date Start Time/End Time Total Time Will Need Additional Session

#1 Date _____ Total _____ Likely - Maybe - Unlikely

% Solution Used _____ Was more than 0.5 ml solution injected in any site: NO _____ YES _____ Where: _____

Any complications noted: NO _____ YES _____ Details: _____

#2 Date _____ Total _____ Likely - Maybe - Unlikely

% Solution Used _____ Was more than 0.5 ml solution injected in any site: NO _____ YES _____ Where: _____

Any complications noted: NO _____ YES _____ Details: _____

#3 Date _____ Total _____ Likely - Maybe - Unlikely

% Solution Used _____ Was more than 0.5 ml solution injected in any site: NO _____ YES _____ Where: _____

Any complications noted: NO _____ YES _____ Details: _____

#4 Date _____ Total _____ Likely - Maybe - Unlikely

% Solution Used _____ Was more than 0.5 ml solution injected in any site: NO _____ YES _____ Where: _____

Any complications noted: NO _____ YES _____ Details: _____

Physician Signature _____

000042

Nuvo of Spokane

Sclerotherapy Home Care

1. Walk for 5-10 minutes following sclerotherapy to keep blood flowing through the deep veins in your legs.
2. Wear support hose when up and about every day for the next 5 days. The support hose may be worn everyday; they will make your legs feel better.
3. Avoid hot baths or showers for the next 2-3 days.
4. Injected veins will darken after treatment and the skin may discolor. This will usually go away within 4-6 weeks, but it may take longer to resolve.
5. Avoid aspirin and other anti-inflammatory medications as they may increase bruising – take Tylenol for pain control for the next week if needed,
6. You may experience itching following treatments. This will usually resolve within 2-3 hours. Ice packs will help. You may also use a 1% hydrocortisone cream applied 3-4 times a day.
7. Schedule a return appointment in 2-4 weeks following treatment for re-evaluation and removal of any trapped blood from painful veins as needed.
8. If you have any other concerns,
Please call Nuvo of Spokane at 509-927-9400

Redaction Summary (87 redactions)

3 Privilege / Exemption reasons used:

- 1 -- "DOH Licensee Social Security Number - RCW 42.56.350(1)" (2 instances)
- 2 -- "Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1)" (63 instances)
- 3 -- "Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1)" (22 instances)



Page 5, DOH Licensee Social Security Number - RCW 42.56.350(1), 1 instance
Page 6, DOH Licensee Social Security Number - RCW 42.56.350(1), 1 instance
Page 24, Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1), 4 instances
Page 25, Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1), 9 instances
Page 26, Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1), 2 instances
Page 28, Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1), 2 instances
Page 29, Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1), 2 instances
Page 30, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 1 instance
Page 159, Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1), 2 instances
Page 162, Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1), 1 instance
Page 167, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 8 instances
Page 168, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 12 instances
Page 169, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 27 instances
Page 170, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 15 instances