

Compliance Agreement  
Division of Public and Behavioral Health  
Artius Dermatology Associates PC, DBA Lux Dermatology  
Registrant No. 18429

This Compliance Agreement ("Agreement") is made and entered into on \_\_\_\_\_, by and between the Radiation Control Program ("RCP") of the Division of Public and Behavioral Health (hereinafter "Division") and Artius Dermatology Associates PC, DBA Lux Dermatology (hereinafter "ADALD"), Registrant Number 18429.

RECITALS

The goal of this compliance agreement is to make electronic brachytherapy treatments for skin cancers more accessible to patients by reducing the annual registration fee for electron brachytherapy systems used by dermatologists and adding flexibility to the requirement for an authorized user to be present during treatments. Electronic brachytherapy is a type of radiation therapy that uses X-rays which are electronically generated to deliver a radiation dose inside a patient's body or in contact with, or very close to, the body surface.

A. Regulation or Statutory Authority

1. NAC 459.5922(2), provides, in relevant part,

- (a) An authorized user must be physically present during the initiation of all patient treatment or identify in writing an authorized medical physicist for electronic brachytherapy who is trained in the operation and emergency response for the system who will be physically present during the initiation of all patient treatments.
- (b) Shall review the case of a patient to ensure that the therapeutic X-ray procedure is appropriate;
- (c) Shall regularly review the progress of each patient receiving therapy and modify the originally prescribed dose if necessary; and
- (d) Shall prevent the clinical use of a system in which a malfunction has been identified pursuant to the spot check required by NAC 459.5934, until such time as the spot check has been evaluated and the malfunction corrected, or the equipment repaired.

2. NAC 459.161(1)(f) provides, in relevant part,

An application for the registration of a radiation machine submitted pursuant to NAC 459.154 must be accompanied by a non-refundable fee for each X-ray tube, electron source or source of ionizing radiation, which is installed in the radiation machine, as follows:

...

(f) Accelerator, \$550.

3. NAC 459.161(2) states in relevant part,

If the Division issues a registration certificate pursuant to NAC 459.156, the registrant must, for each year the certificate is valid, submit to the Division a nonrefundable renewal fee in an amount equal to the appropriate fee set forth in subsection 1.

4. NAC 459.5931, provides, in relevant part,

- 1. A registrant shall pay an annual fee for the registration and inspection of an electronic brachytherapy device in the amount of \$4,400.

The registration fee is due within 30 days after the acquisition of the electronic brachytherapy system.

2. An annual renewal fee must be paid not later than the date on which the registration expires. If the fee is not received by that date, the registrant shall:
  - (a) Cease operating the radiation machine on that date; and
  - (b) Within 5 days after the registration expires, submit to the Division:
    1. An application for a renewal of the registration;
    2. The fee set forth in subsection 1; and
    3. A fee for late payment that is equal to twice the amount of the registration fee.

#### B. Analysis

NAC 459.5922(2)(a) requires an Authorized User (AU) or an Authorized Medical Physicist (AMP) to be physically present during the initiation of all patient treatments. The AMP develops the radiation treatment plan and performs tests and checks to ensure the electron brachytherapy system is operating correctly. The AU prescribes the radiation treatment, approves the treatment plan, and supervises the operation of the electronic brachytherapy system. The AU must be a physician who is certified in radiation oncology, therapeutic radiology, or radiation therapy. Dermatology offices do not treat enough patients to employ full time AUs or AMPs. To better facilitate treatments, the Agreement will allow ADALD to identify in writing a physician or AMP for electronic brachytherapy who will be physically present during the initiation of all patient treatments. The physician or AMP must be trained in the operation and emergency response for the system. By allowing a physician in addition to an AMP to meet the requirement for an AU to be physically present will give the facility the flexibility to provide treatments using staff who work at the facility full time.

This Agreement will allow ADALD:

- (1) To register electron brachytherapy systems including systems that produce multiple treatment modalities such superficial radiation therapy for dermatology uses at the same fee as an accelerator radiation therapy system, which is currently \$550.00.
- (2) To use a physician who is under the supervision of an AU, is identified in writing, and trained in the operation and emergency response for an electronic brachytherapy system to be physically present during the initiation of all patient treatments.

When the regulations for electronic brachytherapy were developed, there were no electron brachytherapy systems in use for dermatology. Insurance reimbursements for electronic brachytherapy treatments by dermatologists are not enough to support the electron brachytherapy fee of \$4,400.00 per year due to the facility's cost to administer the treatment and the low number of patients treated. The application of radiation to treat skin cancer by dermatologists is like cancer treatments from accelerator radiation therapy systems because the radiation is applied from outside of the patient's body and does not involve inserting a source of radiation inside of the patient. For this reason, the registration fee of \$550.00 for a radiation therapy system better suits the dermatology uses of electron brachytherapy.

- C. The Division supports ADALD's request to reduce the registration fee for electron brachytherapy for the treatment of skin cancer and other conditions by dermatologists and to use a physician under the supervision of an AU, identified in writing, and trained in the operation and emergency response for an electronic brachytherapy system.

D. NAC 439.280 provides, in relevant part:

1. The provisions of NAC 439.200 to 439.270, inclusive, do not preclude a person who is temporarily unable to comply or unable to comply fully with a regulation from negotiating a schedule for compliance.

[...]

3. In those areas of the State which are not in a health district, or in case of a regulation enforced exclusively by the State Board of Health, the Chief Medical Officer may postpone the enforcement of and agree to a schedule for compliance with the regulation. If the period needed by such a person to comply exceeds 45 days, the schedule must be submitted to the State Board of Health for approval.

NOW, THEREFORE, it is hereby agreed as follows:

1. State Licensure.

Upon a determination that ADALD is in full compliance with the statutes and substantial compliance with the regulations, with the exception of the reduction in registration fees and the use of a physician who is under the supervision of an AU, identified in writing and trained in the operation and emergency response for an electronic brachytherapy system to meet the requirement in NAC 459.5922.2 for an AU to be physically present during the initiation of all patient treatments.

2. Terms of Compliance

ADALD can:

(1) Register electron brachytherapy systems including systems that produce multiple treatment modalities such superficial radiation therapy for dermatology uses at the same fee as an accelerator radiation therapy system, which is currently \$550.00.

(2) Use a physician who is under the supervision of an AU, is identified in writing, and trained in the operation and emergency response for an electronic brachytherapy system to be physically present during the initiation of all patient treatments.

3. Term of Agreement.

This Agreement shall remain in effect for a period not to exceed 45 days or can go beyond the 45 days if presented at the earliest Nevada Board of Health meeting for approval. Once submitted to the Nevada Board of Health, and thereafter approved, the Agreement shall remain in effect until such time as the Chief Medical Officer revokes the Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement effective the day and year first above written.

LUX DERMATOLOGY

Signed: Albert Mesa  
Albert Mesa  
Medical Physicist  
Lux Dermatology

Date: Jan. 21, 26

NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

Signed: Ihsan Azzam  
IHSAN AZZAM, Nevada State Health Officer

Date: 2-23-, 26

Approved by Board of Health on:

Signed: \_\_\_\_\_  
JON PENNELL, DVM, Chairperson  
Nevada State Board of Health

Date: \_\_\_\_\_, 26