DEPARTMENT OF HEALTH AND HUMAN SERVICES Division of Public and Behavioral Health





DIVISION OF PUBLIC & BEHAVIORAL HEALTH

Bureau of Health Protection and Preparedness

Radiation Control Program

LCB File No. R043-20 and Errata

Informational Statement per NRS 233B.066

- 1. A clear and concise explanation of the need for the adopted regulation: it is being proposed that NAC regulations related to the Radiation Control Program be amended in the following program areas for the below-stated reasons.
 - Radioactive Materials (RAM). Need to modify existing regulations that prohibit a licensee or certain affiliated persons from engaging in deliberate misconduct or knowingly submitting incomplete or inaccurate information to the Division. (NAC 459.135) Modification of this regulation additionally prohibits a registrant or certain persons affiliated with a registrant from engaging in similar conduct.
 - Radiation Producing Machines (RPM). Need to modify existing regulations to remove the requirement for use of gonadal shielding to address the efficacy and use of gonadal shielding when engaging in radiology.
 - Technologist licensing. Need to modify existing regulations that address the licensing and registration of persons who engage in radiation therapy and radiologic imaging. Provides clarification to the different types of registration and the required documentation to be submitted for registration and renewals. Provides clarification on the requirements for licensure and renewals.
 - Mammography. Need to modify existing regulations to address the late registration of a mammography machine. Authorizes a late fee of \$56 to be charged when renewing the expired registration of a mammography machine. The imposition of a late fee will help with timely renewals and compliance with regulations.
- 2. The Division of Public and Behavioral Health presented several opportunities for the public, regulated community, licensees, registrants and stakeholders to provide input and comments regarding the proposed regulations, including the economic impact the proposed regulations may have on small business and the public. A Small Business Impact Questionnaire using Survey Monkey was emailed to all Radiation Control Program (RCP) licensees and registrants on March 23, 2020. Of approximately 3146 Small Business Impact Questionnaires distributed, 54 responses were received. Fourteen respondents indicated that there was a general adverse economic impact on business and twelve respondents indicated that there was a general indirect adverse effect on business. None of these provided the specific effects. Respondents were contacted

to discuss their specific concerns. Two respondents provided their specific concerns when contacted by the RCP. The RCP reviewed the first respondents concerns and determined that a change was reasonable, and a modification to that regulation was made in the errata. The other respondent had misread a proposed regulation and mistakenly thought that a fee increase was being proposed. A Public Workshop was conducted on August 21, 2020 by means of teleconference to allow for further input by the public and regulated community regarding the proposed regulations and how they will impact small businesses. There were 15 participants. No written comment was received from the public. Verbal comment was received from two members of the public. One person called in late and was not able to voice his concerns as the meeting had ended. He contacted the RCP after the meeting and his concerns were discussed. A summary of comments follows:

- 1. One relating to the submission of registration requirements for a rural authorization certificate.
- 2. Request to the Division to clarify the review process of the publication adopted by reference in Section 10 subsection 1 or 2 when revised. If the Division determines that the revision is not suitable for this State, the Division will consult with the Radiation Therapy and Radiologic Imaging Advisory Committee.
- 3. Disagreement with the requirement to stop operating a registered machine when the registration expires.

All comments were taken into consideration and as applicable the proposed regulations were modified as indicated in the errata.

The proposed regulations in LCB File No. R043-20 were posted on the Division's website with a link provided in the questionnaire. Interested persons can obtain a copy of the Summary by contacting the RCP at (775) 687-7550 in Carson City or by utilizing the link below to our website. http://dpbh.nv.gov/Reg/RPM/Radiation_Producing_Machines_-_Home/

3. The following meetings were conducted:

Public Workshop:

Nevada Division of Public and Behavioral Health (DPBH) Radiation Control Program (RCP) held a Public Workshop on August 21, 2020 to allow for further input by the public and regulated community regarding the proposed regulations prescribed in LCB File No R043-20. The workshop was held via teleconference only pursuant to Governor Sisolak's March 22, 2020, Declaration of Emergency Directive 006, suspending the requirement contained in NRS 241.023(1)(b) that there be a physical location, in order to mitigate the possible exposure or transmission of COVID-19 (Coronavirus). There were 15 participants. No written comment was received from the public. Verbal comment was received from two members of the public listed below.

- Joan Hall
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 Nevada Rural Hospital Partners.
- 2. Jeanette K. Belz

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Board of Health Public Hearing:

NOTICE OF INTENT TO ACT UPON A REGULATION, Notice of Hearing for the Amendment of Regulations of the Department of Health and Human Services (LCB File No. R043-20). The State Board of Health held a public hearing at 9:00 a.m. on December 10, 2020, via videoconference only pursuant to Governor Sisolak's March 22, 2020, Declaration of Emergency Directive 006, suspending the requirement contained in NRS 241.023(1)(b) that there be a physical location, in order to mitigate the possible exposure or transmission of COVID-19 (Coronavirus). The purpose of the hearing was to receive comments from all interested persons regarding amendments to Chapter 457 of Nevada Administrative Code (NAC) Cancer, Chapter 459 of Nevada Administrative Code, Hazardous Materials and Chapter 653 of Nevada Administrative Code, Radiation Therapy and Radiologic Imaging. The regulation changes were heard in the order placed on the State Board of Health agenda. There were 53 participants. No written comment was received from the public. A question was received from one board member asking for clarification on why the requirement to utilize gonadal shielding was being removed from the regulations, it was addressed by the Program Manager, John Follette. No one testified in opposition to the adopted regulations.

- 4. Pursuant to NRS 233B.0608 (2)(a), the Division of Public and Behavioral Health requested input from stakeholders, small businesses, registrants and licensees that are likely to be affected by the proposed regulations. A Small Business Impact Questionnaire utilizing Survey Monkey was emailed to approximately 3146 licensees and registrants of the Radiation Control Program along with a website link to the proposed regulation changes, on March 23, 2020. The questions on the questionnaire were:
 - 1) How many employees are currently employed by your business?
 - 2) Will a specific regulation have an adverse economic effect upon your business?
 - 3) Will the regulation(s) have any beneficial effect upon your business?
 - 4) Do you anticipate any indirect adverse effects upon your business?
 - 5) Do you anticipate any indirect beneficial effects upon your business?

Summary of Response

Summary of Comments Received

(There were { 59 } responses received out of { 3146 } small business impact questionnaires distributed)

(Q#2) Will a specific regulation have an adverse economic effect upon your business?	(Q#3) Will the regulation(s) have any beneficial effect upon your business?	(Q#4) Do you anticipate any indirect adverse effects upon your business?	(Q#5) Do you anticipate any indirect beneficial effects upon your business?
{ 14 } "Yes" Responses	{ 1 } "Yes" Responses	{ 12 } "Yes" Responses	{ 1 } "Yes" Responses
{ 45 } "No" Responses	{ 58 } "No" Responses	{ 47 } "No" Responses	{ 57 } "No" Responses

Comments (Q#2): Summary of comments received to: Will a specific regulation have an **adverse economic** effect upon your business?

- These regulations increase administrative costs significantly.
- As a small facility, any increase in fees and/ or licensing will have an adverse effect toward the facility.
- 100 dollars, the cost of licensure for an unnecessary state licensing requirement. Added hassle from state regulators looking to justify their unnecessary job.

<u>Comments (Q#3): Summary of comments received to:</u> Will the regulation(s) have any **beneficial** effect upon your business?

• Environmental

<u>Comments (Q#4): Summary of comments received to:</u> Do you anticipate any **indirect adverse** effects upon your business?

- Increase cost
- Why limit to 5-days? 30-days is common throughout numerous regulatory agencies. 5-days is a tad ridiculous...
- We are a non-profit organization with limited funds. Also, getting continued education for dental radiography is very limited in our area. If dental radiology is to have continued education and/or an expiration date to the certification it will limit who we can hire without proper course being offered. We are already very limited with other restrictions put in place in addition to being a non-profit.
- We will have to hire X-ray credentialed people to take our spinal radiographs.
- Employees are not RT(ARRT) and will have to be let go

• We could no longer provide X-Rays to underserved areas, and we will not be starting any other medical clinics in this state strictly because of these regulations.

<u>Comments (Q#5): Summary of comments received to:</u> Do you anticipate any **indirect beneficial** effects upon your business?

• We are industrial. Mammography does not apply.

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Glen Gimenez at the Division of Public and Behavioral Health at:

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

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- 5. After consideration of public comment, the proposed regulation was revised based on feedback from multiple individuals throughout the development process. The major changes included:
 - 1) The Radiation Control Program revised proposed regulation to clarify the review process of the publications adopted by reference in Section 10, subsection 1 or 2 when revised. If the Division determines that the revision is not suitable for this State, the Division will consult with the Radiation Therapy and Radiologic Imaging Advisory Committee.
 - 2) The Radiation Control Program revised proposed regulation to: eliminate the 5-day allowance for mail in registration renewal; removed the provision to stop operating a radiation machine with an expired registration; addressed concerns with late registration renewals by replacing mail in renewals with immediate online electronic renewals; and, provides for online notification of a change in status to registered machines.

After consideration, the proposed regulations and fees were adopted by the Board of Health without change.

- 6. Anticipated effects on the business which NAC 457, 459, 653 and R043-20P regulates:
 - (a) *Adverse effects:* May have a negative economic impact on licensees, registrants and stakeholders that have deficient practices that lead to an administrative sanction.
 - (b) *Beneficial:* Clearly defines what is expected of the regulated community; protects the public from unnecessary exposure to harmful ionizing radiation; and, amends and modifies existing language to make regulations more clear, current and compatible with the intent and scope of the Radiation Control Program.

- (c) *Immediate*: The stated adverse and beneficial effects would be immediate impacts, as soon as the proposed regulations become effective.
- (d) *Long-term*: The long-term impacts would be the same as the immediate impacts as it would not be expected that the impacts would go away.

There are no estimated economic effects of the proposed regulations on the public. The Legislature and the Division determined that any impact on the public would be appropriately justified to meet the needs of the community.

- (a) Adverse effects: None Anticipated.
- (b) Beneficial effects: Increased public health and safety.
- (c) Immediate effects: Increased public health and safety.
- (d) Long-term effects: Increased public health and safety.
- 7. There is no estimated cost to the Division of Public and Behavioral Health for enforcement of the proposed regulations. Enforcement of the proposed regulations will be incorporated into current administrative, registration, licensing and inspection processes.
- 8. The proposed regulations do not overlap or duplicate any other State of Nevada regulations.
- 9. The proposed regulations are not more stringent than federal regulation.
- 10. The amendments and proposed regulations as approved provide for a late fee of \$56 to be charged for late registration of a mammography machine. The approximate total annual amount the agency collects cannot be predetermined; it will depend on the number of late registrations received. The fees collected will provide for staff members assigned to the program and support the online licensing system. The administrative staffs' time includes reviewing applications issuing registrations, the processing of payments, database entry, billing assistance using the online licensing system, and general customer service.