

Comments Submitted for 1/19/2021 Workshop Consideration
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Current NCCR	Comment	Recommendation
<p>12.065 Cannabis treated with radiation. If any cannabis or cannabis product has been treated with radiation at any time, any and all packaging of the irradiated cannabis or cannabis product must include labeling that contains the following statement: “NOTICE: This product contains ingredients that have been treated with irradiation” in bold lettering, along with the Radura symbol as used by the U.S. Food and Drug Administration</p>	<p>A. Regulatory Authority</p> <p>Nevada, being an agreement State, assigns all activities related to the use of radioactive material to the purview of Department of Health and Human Services Division of Public and Behavioral Health. NRS 459 clearly designates such responsibility. NCCR section 12.065 does not correlate with, and therefore supplants that regulatory authority in Nevada.</p> <p>B. Scope</p> <p><i>NAC 459.068 “Radiation” defined. (NRS 459.201) “Radiation” means ionizing radiation, that is, gamma rays and X-rays, alpha and beta particles, high speed electrons, neutrons and other nuclear particles.</i></p> <p>Assuming NCCR Section 12.065 invokes the NAC 459.068 definition, the text implies permission to use ionizing radiation, that is, gamma rays and X-rays, alpha and beta particles, high speed electrons, neutrons and other nuclear particles to treat cannabis. This wide application ignores the reality that the some of these “radiations”, such as alpha and beta particles and neutrons are impractical for any treatment/irradiation of cannabis; it also creates coordination difficulties for the governing regulatory authority.</p>	<p>Delete section 12.065.</p>

	<p>C. Treatment/Irradiation of Cannabis</p> <p>While a radiation control program (thus the radiation-producing machines) would be under the purview of Department of Health and Human Services Division of Public and Behavioral Health, no regulatory specifications exist within that department for radiation/irradiation of cannabis. Nevada Department of Agriculture refers irradiation of seeds to FDA (NRS 587.889.2.(k)). At a glance, Department Food and Drug Administration (FDA) does specify certain requirements applicable to radiation/irradiation of food and food additives. However, the irradiation of cannabis is not addressed under any of those requirements.</p> <p>At the designated extremely low dose, radiation is very effective to reduce or eliminate microorganisms that may harm the consumer. The implied assumption that treating cannabis with radiation/irradiation will result in harmful residues is unfounded. Currently, the ionizing radiation for the treatment of food is limited to gamma-rays, electrons, and X-rays (21 CFR 179.26). There are also radiofrequency radiations, including microwave frequencies, ultraviolet radiation, and pulsed light (21 CFR 179.30~41). All these treatments, when used per regulations, are considered safe without harmful effects to consumers.</p> <p>D. “NOTICE: This product contains ingredients that have been treated with</p>	
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	<p>irradiation”</p> <p>This “NOTICE” is very misleading. 21 CFR 179.26(b) delineates a threshold for radiation/irradiation dose levels before a labeling requirement is applicable. NCCR 12.065 applies the FDA food labeling requirements to irradiated cannabis without any dose level threshold. As such, the “NOTICE” not only provides zero added value for public health protection, it will falsely create a perception of potential harm.</p> <p>Additionally, FDA does not require that individual ingredients in multi-ingredient foods (e.g., spices) be labeled. Cannabis production products, such as candies, drinks, and lotions are all multi-ingredient products.</p> <p>The FDA clearly states in its Food Irradiation: What You Needs to Know that <i>“Food irradiation does not make foods radioactive, compromise nutritional quality, or noticeably change of the taste, texture, or appearance of food.”</i> <i>“Food irradiation ...improves the safety and extends the shelf life of foods by reducing or eliminating microorganisms...”</i></p> <p>Further, in its draft publication “Cannabis and Cannabis-derived Compounds: Quality Considerations for Clinical Research Guidance for Industry (July 2020),” FDA outlines the current thinking on cannabis and cannabis-derived compounds. It is that they “may be used in drug manufacturing include botanical raw materials, extracts, and highly purified substances of botanical</p>	
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	<p>origin.” Thus, it clearly excludes cannabis as food.</p> <p>Cannabis in Nevada is not a food. An unprecedented regulation with such complexity involving radiation/irradiation and FDA food-labeling requirements should not be made unilaterally without legislative considerations and processes.</p>	
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