

AGENCY MEMORANDUM OF RESPONSE

TO: Jacob Ritzenthaler, Regulatory Policy Advocate

CC: Carrie Kuruc
Director of the Common Sense Initiative Office Ohio Lieutenant Governor

FROM: Lisa Eschbacher
Deputy General Counsel
Ohio Department of Health

RE: Medical Use of Radioactive Materials
(OAC Chapter Rules 3701:1-40-16, 3701:1-46-43, 3701:1-58-01, 3701:1-58-07 through 3701:1-58-10, 3701:1-58-12, 3701:1-58-15, 3701:1-58-16, 3701:1-58-18 through 3701:1-58-21, 3701:1-58-26, 3701:1-58-33, 3701:1-58-35, 3701:1-58-36, 3701:1-58-37, 3701:1-58-40 through 3701:1-58-43, 3701:1-58-49, 3701:1-58-51 through 3701:1-58-55, 3701:1-58-58, 3701:1-58-69, 3701:1-58-71, 3701:1-58-73, 3701:1-58-86, 3701:1-58-100, 3701:1-58-101, 3701:1-58-104, and 3701:1-58-105)

DATE: November 21, 2019

Thank you for permission to move forward with Original Filing O.A.C. Rules 3701:1-40-16, 3701:1-46-43, 3701:1-58-01, 3701:1-58-07 through 3701:1-58-10, 3701:1-58-12, 3701:1-58-15, 3701:1-58-16, 3701:1-58-18 through 3701:1-58-21, 3701:1-58-26, 3701:1-58-33, 3701:1-58-35, 3701:1-58-36, 3701:1-58-37, 3701:1-58-40 through 3701:1-58-43, 3701:1-58-49, 3701:1-58-51 through 3701:1-58-55, 3701:1-58-58, 3701:1-58-69, 3701:1-58-71, 3701:1-58-73, 3701:1-58-86, 3701:1-58-100, 3701:1-58-101, 3701:1-58-104, and 3701:1-58-105 with JCARR. This rule package consists of 37 amended rules and one new rule proposed by the Ohio Department of Health (ODH). This rule package was submitted to the CSI Office on August 14, 2019 and the public comment period was held open through September 12, 2019. No comments were received during this time. The rules contained in this package establish requirements for the possession and use of radioactive material for medical use. These rules set forth the terms and conditions for radioactive material licenses to include requirements for licensees to report instances of generator breakthrough or contamination; provide guidelines for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs and includes provisions that ensure registration status, labeling, and pharmacist designation; details the application and renewal processes for licensure and is being amended to clarify the information required on an application; set forth requirements for license amendments, notification, and exemptions and are largely being amended to reflect the inclusion of associate radiation safety officers and ophthalmic physicists; establishes the authority and responsibility of the radiation protection program and is being amended to allow for the appointment of associate radiation safety officers; and establish training and safety requirements for various treatments, including the use of unsealed radioactive material, administration of radioactive medication, and safety procedures for equipment. There are 300 licensees currently operating in Ohio. The adverse costs created by the rules include the time and effort spent by licensees to comply with the training and handling requirements of the rules, however many of the amendments made to the rules increase flexibility for licensees.