### DATE: 02/12/2020 3:45 PM

### ACTION: Original NOTICE OF PUBLIC RULES HEARING

DATE:	Friday, March 19, 2020
TIME:	11:00 a.m.
LOCATION:	Ohio Department of Health
	35 E. Chestnut Street
	Columbus, Ohio 43215
ROOM:	ODH Basement Training Room A

In accordance with *Chapter 119* of the Revised Code (R.C.), the Director of the Ohio Department of Health announces a Public Hearing at the date and time listed above to hear comments regarding the following action:

### Ohio Revised Code (O.A.C.) Chapter 3701:1-50 – Packaging and Transportation of Radioactive Materials.

The proposed rules are under review as required by Ohio Revised Code 119, these rules concern R.C. 3748.04 which discusses the requirements, procedures and fees dealing with types of radiation-generating equipment and the registration by its handler. The legislation requires the Ohio Department of Health to adopt rules establishing these standards and procedures.

#### Information regarding rule package proposed:

This Ohio Department of Health (Department) rule package consists of thirteen amended rules and eight no-change rules proposed by the Ohio Department of Health (ODH). This rule package was submitted to the CSI Office on October 22, 2019 and the public comment period was held open through November 22, 2019. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI office on October 22, 2019.

Ohio Administrative Code (OAC) Chapter 3701:1-50 establishes regulations related to the packaging and transportation of radioactive material. OAC 3701:1-50-01 through OAC 3701:1-50-04 set forth the definitions used throughout the Chapter, the scope of the regulations, and record keeping and licensing requirements. OAC 3701:1-50-05 and 3701:1-50-06 state general transportation requirements and exemptions for materials with only low levels of radiation. OAC 3701:1-50-07 and OAC 3701:1-50-10 through 3701:1-50-12 establish general licenses for certain types of material transport, including packages approved by the United States Nuclear Regulatory Commission and fissile material. OAC 3701:1-50-13, 3701:1-50-15, 3701:1-50-16, and 3701:1-50-17 establish regulations regarding exemptions, determinations of shipped packages, and assumptions of unknown properties. OAC 3701:1-50-18 describes the requirements for plutonium to be transported by air. OAC 3701:1-50-20 and 3701:1-50-23 through 3701:1-50-26 concern the remaining recordkeeping, notification, exemption, and quality assurance requirements for licensees. The amendments to the rules in this package are largely being made to update references to federal regulations.

# Ohio Revised Code (O.A.C.) Chapter 3701:1-40-16, 3701:1-46-43, and 3701:1-58 – Medical Use of Radioactive Materials

The proposed rules are under review as required by Ohio Revised Code 3748.02 and 3748.04, these rules designate The Ohio Department of Health as the radiation control agency, as well as discuss the requirements, procedures and fees dealing with types of radiation-generating equipment and the registration by its handler. The legislation requires the Ohio Department of Health to adopt rules establishing these standards and procedures.

### Information regarding rule package proposed:

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

10/3/2019

## **NOTICE OF PUBLIC RULES HEARING**

12, 2019. No comments were received during this time. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI office on August 14, 2019.

The rules contained in this package establish requirements for the possession and use of radioactive material for medical use by providing guidelines for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs; establishes requirements for medical use of radioactive materials; details the application and renewal processes for licensure; establishes the authority and responsibility of the radiation protection program, as well as many other requirements and procedures, however the amendments made to the rules increase flexibility for licensees.

### Hearing and Contact Information:

At the hearing, people affected by the proposed action may appear and be heard in person or accompanied by an attorney. They may present their positions, arguments, or contentions orally or in writing; may offer witnesses; and may present evidence showing that the proposed rule, if adopted or effectuated, will be unreasonable or unlawful.

To aid in getting visitors through building security, any persons intending to testify at the hearing or planning to observe are encouraged to pre-register by writing to the Office of the General Counsel, Ohio Department of Health, 246 North High Street, 7th Floor, Columbus, Ohio 43215, or by phone to (614) 466-4882, or send an e-mail to <u>odhrules@odh.ohio.gov</u>.

Copies of will Register of Ohio website: the proposed rules be available the on http://www.registerofohio.state.oh.us/rules/search approximately one day after the rule is filed, or from the Office of the General Counsel, Ohio Department of Health (https://odh.ohio.gov/wps/portal/gov/odh/about-us/offices-bureaus-anddepartments/Office-of-General-Counsel/laws-and-rules/).

Please e-mail any written comments to <u>ODHRules@odh.ohio.gov</u> by 5:00 p.m. on March 17, 2020.