Rule Summary and Fiscal Analysis (Part A)

Department of Health
Agency Name

Radiation Control | **Lance D. Himes**
Division | Contact

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3701:1-46-42 | **NO CHANGE**
Rule Number | TYPE of rule filing

Rule Title/Tag Line: **Manufacture and distribution of radioactive material for certain in-vitro clinical or laboratory testing under general license.**

RULE SUMMARY

1. Is the rule being filed consistent with the requirements of the RC 119.032 review? **Yes**

2. Are you proposing this rule as a result of recent legislation? **No**

3. Statute prescribing the procedure in accordance with the agency is required to adopt the rule: **119.03**

4. Statute(s) authorizing agency to adopt the rule: **3748.04**

5. Statute(s) the rule, as filed, amplifies or implements: **3748.04**

6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

ODH reviewed this rule pursuant R.C. 119.032 and to assure compatibility with federal regulations; no changes are proposed for this rule.

7. If the rule is an AMENDMENT, then summarize the changes and the content of the proposed rule; If the rule type is RESCISSION, NEW or NO CHANGE,

then summarize the content of the rule:

This rule sets forth requirements for manufacture and distribution of radioactive material for certain in-vitro clinical or laboratory testing under general license.

8. If the rule incorporates a text or other material by reference and the agency claims the incorporation by reference is exempt from compliance with sections 121.71 to 121.74 of the Revised Code because the text or other material is **generally available** to persons who reasonably can be expected to be affected by the rule, provide an explanation of how the text or other material is generally available to those persons:

This rule references sections of the Ohio Administrative Code. The O.A.C. is generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule.

9. If the rule incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material electronically, provide an explanation of why filing the text or other material electronically was infeasible:

Ohio Revised Code 121.76 exempts agencies from filing copies of Ohio law and regulations cited in the text of a rule.

10. If the rule is being **rescinded** and incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material, provide an explanation of why filing the text or other material was infeasible:

Not Applicable.

11. If **revising** or **refiling** this rule, identify changes made from the previously filed version of this rule; if none, please state so. If applicable, indicate each specific paragraph of the rule that has been modified:

Not Applicable.

12. 119.032 Rule Review Date: **9/18/2012** and **09/15/2017**

(If the rule is not exempt and you answered NO to question No. 1, provide the scheduled review date. If you answered YES to No. 1, the review date for this rule is the filing date.)

NOTE: If the rule is not exempt at the time of final filing, two dates are required:

the current review date plus a date not to exceed 5 years from the effective date for Amended rules or a date not to exceed 5 years from the review date for No Change rules.

FISCAL ANALYSIS

13. Estimate the total amount by which *this proposed rule* would **increase / decrease** either **revenues / expenditures** for the agency during the current biennium (in dollars): Explain the net impact of the proposed changes to the budget of your agency/department.

This will have no impact on revenues or expenditures.

$0.00

Not applicable

14. Identify the appropriation (by line item etc.) that authorizes each expenditure necessitated by the proposed rule:

Not applicable

15. Provide a summary of the estimated cost of compliance with the rule to all directly affected persons. When appropriate, please include the source for your information/estimated costs, e.g. industry, CFR, internal/agency:

Not applicable

16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? **No**

17. Does this rule deal with environmental protection or contain a component dealing with environmental protection as defined in R. C. 121.39? **No**

S.B. 2 (129th General Assembly) Questions

18. Has this rule been filed with the Common Sense Initiative Office pursuant to R.C. 121.82? **Yes**

19. Specific to this rule, answer the following:

A.) Does this rule require a license, permit, or any other prior authorization to

engage in or operate a line of business? **Yes**

This rule requires the need for a specific radioactive material license

B.) Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms? **No**

C.) Does this rule require specific expenditures or the report of information as a condition of compliance? **Yes**

As a condition of licensing, this rule requires specific labeling of pre-packaged units.