Michigan Office of Administrative Hearings and Rules
Administrative Rules Division (ARD)

611 W. Ottawa Street
Lansing, MI 48909
Phone: 517-335-8658 Fax: 517-335-9512

REQUEST FOR RULEMAKING (RFR)

1. Department:
Labor and Economic Opportunity

2. Bureau:
MIOSHA

3. Promulgation type:
Full Process

4. Title of proposed rule set:
Hand-held portable Dental X-Ray Systems

5. Rule numbers or rule set range of numbers:
R 333.5396

6. Estimated time frame:
12 months

Name of person filling out RFR:
Shannon Matsumoto

E-mail of person filling out RFR:
matsumotos@michigan.gov

Phone number of person filling out RFR:
517-284-7734

Address of person filling out RFR:
530 W. Allegan St, Lansing, MI 48933

7. Describe the general purpose of these rules, including any problems the changes are intended to address.

To amend existing rules to allow for the routine use of handheld devices. The rule would prohibit the use of a handheld dental x-ray system to perform dental radiography unless the machine is registered and the system, personnel operating the system, and facility in which the system is being used meet all of the following requirements.

-The system has been approved for human use by the U.S. Food and Drug Administration (FDA) and is used consistently with the approval.
-The system has a backscatter shield that meets all of the following requirements:
-The shield is composed of a leaded polymer or a lead-equivalent substance that has a substantially equivalent protective capacity.
-The shield is permanently affixed to the system.
-The system is certified by its manufacturer before its first use and is calibrated at least every 24 months after the date of the last certification.
-When not in use, the system is stored in a manner that restricts access to the system, such as by storing the system in a locked area of the facility. (An individual using the machine need not use a lead apron or other personal monitoring equipment, but that equipment must be available for use).
-The equipment may not be used if the backscatter shield described above is broken.

The proposed changes are a result of legislative change.

8. Please cite the specific promulgation authority for the rules (i.e. department director, commission, board, etc.).

The department has the authority to promulgate rules. The Public Health Code 368 PA 1978, MCL 333.13521.

A. Please list all applicable statutory references (MCLs, Executive Orders, etc.).

The Public Health Code, 1978 PA 368, Part 135, MCL 333.13515, MCL 333.13521, MCL 333.13522, and MCL 333.13527. Executive Reorganization Order Nos. 1996-1, 1996-2, 2003-1, and 2019-3, being MCL 330.3101, MCL 445.2001, MCL 445.2011, MCL 445.2030, and MCL 125.1998.

B. Are the rules mandated by any applicable constitutional or statutory provision? If so, please explain.

The Public Health Code, 1978 PA 368, MCL 333.13521.

9. Please describe the extent to which the rules conflict with or duplicate similar rules, compliance requirements, or other standards adopted at the state, regional, or federal level.

MIOSHA is not aware of any conflicts or duplications.

10. Is the subject matter of the rules currently contained in any guideline, handbook, manual, instructional bulletin, form with instructions, or operational memoranda?

None that MIOSHA is aware of.

11. Are the rules listed on the department's annual regulatory plan as rules to be processed for the current year?

Yes

12. Will the proposed rules be promulgated under Section 44 of the Administrative Procedures Act, 1969 PA 306, MCL 24.244, or under the full rulemaking process?

Full Process

13. Please describe the extent to which the rules exceed similar regulations, compliance requirements, or other standards adopted at the state, regional, or federal level.

The rules do not exceed similar regulations, compliance requirements, or other standards adopted at the state, regional, or federal level.

14. Do the rules incorporate the recommendations received from the public regarding any complaints or comments regarding the rules? If yes, please explain.

No.

15. If amending an existing rule set, please provide the date of the last evaluation of the rules and the degree, if any, to which technology, economic conditions, or other factors have changed the regulatory activity covered by the rules since the last evaluation.

These rules were created December 5, 2007, and have not been amended until now. The propose changes are a result of legislative change.

16. Are there any changes or developments since implementation that demonstrate there is no continued need for the rules, or any portion of the rules?

No.

17. Is there an applicable decision record (as defined in MCL 24.203(6) and required by MCL 24.239(2))? If so, please attach the decision record.

No