

**MARYLAND DEPARTMENT OF THE ENVIRONMENT
RADIOLOGICAL HEALTH PROGRAM
1800 Washington Boulevard • Baltimore Maryland 21230
(410) 537-3000 • Fax: 410-537-3198 • www.mde.maryland.gov**

APPLICATION FOR USE OF HAND-HELD DENTAL RADIATION MACHINE

Name of Facility: _____ Registration No. _____

Address: _____

City, State, Zip Code: _____

Phone Number: _____ Fax Number: _____ E-mail Address: _____

Contact Person, Title: _____

The following information must be submitted to the Department to request approval for use of a hand-held radiation machine:

1. A signed "Conditions for Use of Hand-Held Radiation Machines" form. (see page 2)
2. A statement by the facility owner indicating **under what circumstances the hand-held radiation machine will be used**, and a description of **where and how the device will be stored when not in use**.
3. **Documentation of manufacturer's training** for all individuals who will operate the device.
4. Documentation, such as a purchase agreement, RX24, or FDA2579, that shows the **date** the hand-held radiation machine was placed in the office, the **serial number**, and **date of manufacture**.
5. An updated "Radiation Machine Facility Registration Form" (**RX-1**).
6. If the total number of machines at a facility is increasing, a **Payment Transmittal Form** and registration fee of **\$80.00 per additional tube** must be submitted.

The complete application should be mailed to:

Maryland Department of the Environment
Radiological Health Program
P.O. Box 2198
Baltimore, MD 21230

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CONDITIONS FOR USE OF HAND-HELD RADIATION MACHINES

The following is a list of conditions placed on the facility for a request to own and operate a hand-held dental radiation machine as part of the facility's registration:

1. Only a United States Food and Drug Administration (**FDA**) approved hand-held radiation machine can be utilized.
2. A hand-held radiation machine is allowed in dental offices as a replacement for or in addition to the use of a wall-mounted or free-standing portable dental radiation machine, **for use when it is determined by the dentist that it is not possible or not safe to utilize a wall mounted or portable stand mounted radiation machine.** NOTE that at least one wall mounted or portable stand mounted radiation machine is required in the dental office.
3. A log of hand-held usage must be maintained on a form provided by the Radiation Machines Division (RMD).
4. Hand-held radiation machine requires dental film speed E or faster or with digital imaging.
5. Each individual operating the device must complete the manufacturer's training and submit the training certificates to the Department. The records will be maintained by the RMD as part of the facility registration.
6. When registering the device, the facility must indicate to the RMD that the intended manner of use is for hand-held operation.
7. The device shall be locked up after use and a description of where and how the device will be stored must be provided to the Department.
8. The device must be in lock down (Safety) mode when it is not active so that exposures cannot be taken.
9. The device used shall have a **permanently mounted non-removable shield** in order to protect the operator from backscatter.
10. Only those persons licensed to operate radiographic equipment in the State of Maryland are permitted to make exposures using this device.
11. The operator must wear a whole body dosimeter when taking an exposure at all times.
12. As low as reasonably achievable (ALARA) practices will be in place during use.
13. The RMD reserves the right to perform an unannounced audit to ensure that the hand held dental device is correctly being utilized.
14. If the device is missing or stolen, the facility must report this to the RMD.

The facility attests that these conditions will be implemented and followed.

Print Name of Facility Owner

Signature of Facility Owner

Date