REQUEST FOR HANDHELD X-RAY WAIVER

Please complete and include this form with your handheld equipment training certificates and written radiation protection program and submit to the address at the bottom of this form. Please call if there are any questions.

Please print or type information below:

Registration # *(if it has been assigned by KDHE)*:

Name of Facility:

Address:

City, State, ZIP:

Contact Name:

Contact Phone number:

Contact Email:

In accordance with K.A.R. 28-35-242. General requirements. (a) Waiver of requirements. This request to use handheld x-ray devices will not constitute a significant risk to the health and safety of the public if the following conditions are met:

(Please answer each question that follows the numbered conditions.)

1. **The registrant shall complete and submit to KDHE, the "RH-92 – Request for Handheld X-ray Waiver" form. The portable handheld dental x-ray system shall not be used by registrant until waiver is signed by all parties.**
   a. Are you currently using the portable handheld dental x-ray system to image patients? ☐Yes ☐No
2. **Portable handheld dental x-ray equipment shall only be purchased from vendors or manufacturers who received an approval waiver from KDHE.**
   a. Does your vendor have an approval waiver from KDHE? ☐Yes ☐No
   b. What is the name of the vendor or manufacturer who provided the unit? _____
3. **The portable handheld dental x-ray system being used must have received FDA approval and will be used in a manner consistent with that FDA approval.**
   a. Does your portable handheld dental x-ray system have FDA approval**?** ☐Yes ☐No
   b. Will your portable handheld dental x-ray system be used in a manner consistent with that FDA approval? ☐Yes ☐No
4. **The registrant shall register the handheld dental x-ray unit with this department within 30 days of purchase and pay all applicable fees.**
   a. Has the registration fee been paid for this portable handheld dental x-ray unit? ☐Yes ☐No
   b. Is this portable handheld dental x-ray unit in addition to your current registration or a replacement for another dental intraoral unit? ☐ Addition ☐ Replacement for another unit

c. If the portable handheld dental x-ray unit is a replacement for another unit(s), have you notified KDHE of the change and completed an X-ray Change of Status form?

☐ I have notified KDHE

☐ I have completed an x-ray change of status form

5. **Each individual operating the device shall complete the training provided by the manufacturer or other training approved by KDHE and pass an exam, <u>prior to use</u>. A certificate or other documentation demonstrating completion of approved training shall be kept on file where the device is registered. Copies of the certificates shall be submitted with the "RH-92 – Request for Handheld X-ray Wavier" form. A completed training certificate shall be posted for each operator at the facility in an area that is visible to patients.**

   a. Has each individual operator completed training for this device? ☐Yes ☐No

   b. Who provided this training to the operator? _____

   c. Was an exam of the training material provided to each operator? ☐Yes ☐No

   d. Did each operator pass this exam? ☐Yes ☐No

   e. Is there a certificate or documentation proving the operator completed their training? ☐Yes ☐No

   f. Is a copy of each certified operator certificate posted at your facility in an area visible to patients? ☐ Yes ☐ No

   g. Is documentation of this training maintained at this facility for review? ☐ Yes ☐ No

6. **The registrant's written radiation protection program shall address the use of a hand held dental x-ray unit. A copy of the registrant's written radiation protection program shall be submitted along with the "RH-92 – Request for Handheld X-ray Waiver" form. This written radiation protection programs shall include, at a minimum, the following: radiation safety, dosimetry, lead shielding of patients and operators, specific training on the equipment and policies and procedures pertaining to new operators of the equipment.**

   a. Does your facility have a written radiation protection program? ☐Yes ☐No

   b. Does your written radiation protection program include the minimum requirements as listed above? ☐Yes ☐No

   c. Have you included a copy of the written radiation protection program for review? ☐Yes ☐No

7. **The registrant shall follow all manufacturer's maintenance and calibration procedures for the unit as specified in the owner or user's manual. If the manual does not give a specific timeframe for calibration or maintenance of the device, the device shall be evaluated by a qualified physicist or service engineer at least every three years.**

   a. Do you have a copy of the owner or user's manual for the portable handheld x-ray unit? ☐ Yes ☐ No

   b. What does the owner or user's manual state as the timeframe for calibration or maintenance of the device? ☐ Annual calibration or maintenance ☐ No stated timeframe in manual (every 3 years)

   c. Do you agree to manufacturer's maintenance and calibration of the device? ☐Yes ☐No

8. **During operating hours, the handheld dental x-ray equipment shall be secured in "lock mode" as described in the operator or user's manual when not in use to prevent exposure by a non-authorized user. The unit shall remain in "lock mode" when not in use. Each operator of the unit <u>will not</u> unlock the unit until the operator is ready to take an exposure.**

   a. Does your device have a means to be placed in an X-ray Lock Mode? ☐Yes ☐No

b. Does this X-ray Lock Mode prevent the unauthorized production of x-rays? ☐Yes ☐No

c. Are all operators aware of how to use the "lock mode?" ☐Yes ☐No

d. Do you agree to use the "lock mode" of the device until it is in active use? ☐Yes ☐No

9. If the unit requires charging during operating hours the charging station shall be in an "employee only access area" or under lock and key. (For example: sterilization room, lab area, doctor's office area) The unit shall be kept in this secure area when not in actual use.

a. Will you charge the unit in an "employee only access area" or under lock and key? ☐ Yes ☐No

b. Do you agree to keep this device in this secure area when not in actual use? ☐ Yes ☐ No

10. After operating hours, such as evenings and weekends, equipment shall be secured by two independent controls or two physical barriers. (For example: locked cabinet in a locked room or separate the battery from the unit with separate storage for both the unit and the battery)

a. Describe how the device will be locked up at the end of each day?_____

_____

b. Does this include two independent controls or two physical barriers? ☐Yes ☐No

c. If the device has a handset or battery that that is removable, do you remove it from the device at the end of each day? ☐Yes ☐ No ☐ N/A, Battery is not removable

d. If the device has a handset or battery that is removable, is the handset or battery stored separately from the unit at the end of each day? ☐Yes ☐ No ☐ N/A, Battery is not removable

11. Operators shall wear a lead apron and thyroid collar during exposure. The patient shall also be protected by a lead apron during exposure.

a. Do you have a full lead apron and thyroid collar for the operator to wear during exposure? ☐ Yes ☐ No

b. Will you protect the patient with a lead apron during exposure? ☐Yes ☐No

12. The backscatter shield provided by the manufacturer, which provides not less than 0.25 mm lead equivalent, must be permanently affixed in place at all times. The x-ray system shall not be used if this component becomes broken or dislodged.

a. Is the protective shield left at the outer edge of the cone during each use? ☐Yes ☐No

b. Do positioning kits allow for the shield to stay at the outer edge of the cone at all times?

☐ Yes ☐ No

c. Do you agree to take the unit out of service if the shield is broken or dislodged? ☐Yes ☐No

13. A handheld dental x-ray unit shall be held without motion during a patient examination. If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a tripod or tube stand to immobilize the device.

a. Do you agree to use a tripod or tube stand to immobilize the device if an operator has difficulty in holding the device stationary during the exposure? ☐Yes ☐No

14. **The handheld dental x-ray unit shall only be used in treatment areas and shall not be used for patient examinations in hallways and waiting rooms. The operator shall ensure there are no bystanders within a radius of at least six feet from the patient being examined with a handheld dental x-ray unit or bystanders shall be protected by a barrier of at least one-inch gypsum or lead equivalent.**

    a. Do you agree to use the handheld dental x-ray unit only in treatment areas and NOT in hallways or waiting rooms? ☐Yes ☐No

    b. Will your operators ensure there are no bystanders within a radius of at least 6 feet from the patient being examined? ☐Yes ☐No

    c. If it is not possible for a bystander to be at least 6 feet from the patient being examined, will they be protected by a barrier of at least one-inch gypsum or lead equivalent? ☐Yes ☐No

15. **A copy of all correspondence with KDHE, unit manufacturer, vendor and registrant shall be maintained by the registrant for review during the next inspection. These documents shall be maintained for the life of the business.**

    a. Do you agree to keep a copy of all correspondence with KDHE, unit manufacturer, vendor and service representative for the life of the business? ☐ Yes ☐ No

16. **The approved unit shall only be used at the registered location. If the unit is to be used at multiple locations, KDHE shall be notified in writing of all locations of use before the use occurs. If the unit will be used in one or more other facilities, the registrant must notify the Radiation Safety Officer(s) that the unit will be in their facility. (Ex. Surgery center or hospital)**

    a. Is the device being used at **ONLY** the location stated above? ☐ Yes ☐ No

    If not, please list the name of the facility and address of each facility: _____

    _____

I hereby agree that only handheld x-ray device(s) identified in this request meeting these conditions will be used by the facility stated above and all personnel operating such devices will comply with conditions of this waiver.

Signature of individual authorized on behalf of the registrant named in this request:

_____ _____

Signature *Date*

_____

Print Name

Submit this completed five-page form, training certificates, and copy of written radiation protection program to:

Kansas Department of Health and Environment
Bureau of Community Health Systems, Radiation Control Section
1000 SW Jackson, Suite 330, Topeka, KS 66612-1365
Phone 785-296-1560 Fax 785-559-4251
kdhe.xray@ks.gov

LIST OF HANDHELD X-RAY UNITS

Please complete this form with information on each handheld x-ray unit. This information can be found on the x-ray unit as well as the "Report of Assembly" or FDA Form 2579 that the installer has provided to you after your purchase of the x-ray unit. Use additional pages for more handheld x-ray units.

Device Manufacturer:
Device Model:
Device Serial Number:
Device Date of Manufacture:

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