

SENATE BILL No. 463

By Committee on Ways and Means

2-20

1 AN ACT concerning health and healthcare; relating to x-ray systems;
2 providing requirements for the use of handheld portable x-ray systems;
3 clarifying powers, duties and functions of the secretary of health and
4 environment.

5
6 *Be it enacted by the Legislature of the State of Kansas:*

7 Section 1. (a) As used in this section:

8 (1) "Handheld portable x-ray system" means an x-ray system
9 designed to be hand-carried and handheld during use without a fixed
10 mounting or stand.

11 (2) "Portable x-ray system" means an x-ray system designed to be
12 hand-carried, but not handheld during use.

13 (b) Prior to use, a handheld portable x-ray system shall:

14 (1) Be approved for human use by the United States food and drug
15 administration and be used in a manner consistent with that approval;

16 (2) have received approval by the department of health and
17 environment in accordance with a waiver granted under K.A.R. 28-35-
18 242; and

19 (3) meet requirements for diagnostic x-ray systems as set forth in
20 K.A.R. 28-35-242b and utilize a backscatter shield that:

21 (A) Is composed of a leaded polymer or a substance with a
22 substantially equivalent protective capacity;

23 (B) has at least 0.25 millimeters of lead or lead-shielding equivalent;
24 and

25 (C) is permanently affixed to the handheld portable x-ray system.

26 (c) The use of a handheld portable x-ray system shall be prohibited if
27 such x-ray system's backscatter shield is broken or is not permanently
28 affixed to the x-ray system.

29 (d) Each individual operating a handheld portable x-ray system shall
30 complete the training provided by the manufacturer of the x-ray system, or
31 other training approved by the department of health and environment, and
32 pass an examination specified by the department of health and
33 environment. A certificate or other documentation demonstrating
34 completion of approved training shall be kept on file where such x-ray
35 system is registered for use.

36 (e) During operating hours when not in use, a handheld portable x-ray

1 system shall be secured in a lock mode as described in the operator or user
2 manual for the x-ray system to prevent exposure by a non-authorized user.
3 Outside of operating hours, a handheld portable x-ray system shall be
4 secured by two independent controls or two physical barriers.

5 (f) A person registering for the operation of a handheld portable x-ray
6 system shall follow the manufacturer's maintenance and calibration
7 procedures for such x-ray system as specified in the operator or user
8 manual. If the manual does not give a specific timeframe for maintenance
9 or calibration, the unit shall be evaluated by a qualified physicist or service
10 engineer at least once every three years.

11 (g) The following rules and regulations, as such rules and regulations
12 exist on the effective date of this section, shall be null and void and shall
13 have no force and effect, and the department of health and environment
14 shall not adopt any rules and regulations that are in substantial conformity
15 with the provisions of the specified rules and regulations:

16 (1) K.A.R. 28-35-242a(a)(8)(C), limiting the use of portable x-ray
17 equipment to situations during which transferring a patient to a stationary
18 x-ray installation is impractical;

19 (2) any rules and regulations limiting utilization of a handheld x-ray
20 system to a dental office or registered location;

21 (3) K.A.R. 28-35-242a(a)(5)(B), imposing shielding requirements for
22 an x-ray operator or other individuals when an x-ray system is used in
23 accordance with manufacturer instructions, unless specifically required by
24 manufacturer instructions or if the x-ray system cannot be used in the
25 intended manner to shield the x-ray operator from backscatter radiation;

26 (4) K.A.R. 28-35-169(b), prescribing shielding requirements for an x-
27 ray operator's booth;

28 (5) K.A.R. 28-35-247a(h)(2), providing that the tube housing and the
29 position indication device shall not be handheld during an exposure; and

30 (6) K.A.R. 28-35-244a(i), requiring that a tube stand or other
31 mechanical support shall be used for portable x-ray systems so that the x-
32 ray tube housing assembly does not need to be handheld during exposures.

33 Sec. 2. This act shall take effect and be in force from and after its
34 publication in the Kansas register.