

State Operations Manual

Appendix D - Guidance to Surveyors: Portable X-Ray Services

(Rev. 28, 09-07-07)

Transmittals for Appendix D

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§486.110 Condition for Coverage: Inspection of Equipment

H0005

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.100 - Condition for Coverage: Compliance with Federal, State, and Local Laws and Regulations

The supplier of portable x-ray services is in conformity with all applicable Federal, State, and local laws and regulations.

Interpretive Guidelines: §486.100

The supplier, its equipment and personnel must be licensed or registered in accordance with applicable Federal, State, and local laws. Review licenses and registration permits to confirm their validity and currency.

X-ray equipment manufactured on or after August 1, 1974, must bear a label indicating it meets FDA standards. If equipment found in use is different from what was described to the SA prior to survey, note the name of the manufacturer (if shown) so that this can be checked out after the survey. Do not show a deficiency unless it has been definitely ascertained that the equipment does not meet FDA Standards.

H0006

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.100(a) Standard - Licensure or Registration of Supplier.

In any State in which State or applicable local law provides for the licensure or registration of suppliers of x-ray services, the supplier is (1) licensed or registered

pursuant to such law, or (2) approved by the agency of the State or locality responsible for licensure or registration as meeting the standards established for such licensure or registration.

H0007

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.100(b) Standard - Licensure or Registration of Personnel

All personnel engaged in operating portable X-ray equipment are currently licensed or registered in accordance with all applicable State and local laws.

H0011

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.100(c) Standard - Licensure or Registration of Equipment

All portable X-ray equipment used in providing portable X-ray services is licensed or registered in accordance with all applicable State and local laws.

H0016

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.100(d) Standard - Conformity with Other Federal, State, and Local Laws and Regulations.

The supplier of portable X-ray services agrees to render such services in conformity with Federal, State, and local laws relating to safety standards.

H0017

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.102 - Condition for Coverage: Supervision by a Qualified Physician

Portable X-Ray services are provided under the supervision of a qualified physician.

Interpretive Guidelines: §486.102

The performance of X-ray tests is subject to the supervision of a physician qualified by advanced training and experience in the use of diagnostic X-rays regardless *of* whether the physician owns the equipment or not. In the event the supervising physician is not listed as the owner and the physician certification required in Standard (a) has not been submitted with the Request for Approval, form CMS-1880, request such certification at survey. Since Standard (a) requires an annual certification by a supervising physician if he is not the owner, ask the supplier to have the certification for the current year available at the time of survey to prevent any delay in certification (see Exhibit 1C).

To confirm that a physician-supervisor specializes in radiology and is recognized by the medical community as a specialist in radiology (Standard (b)), the record should reflect that the physician is:

- (1) Board certified or board eligible in radiology;
- (2) Board certified or board eligible in a medical specialty which includes advanced training in use of X-rays, e.g., the American Board of Orthopedic Surgery, the American Board of Internal Medicine, the American Board of Physical Medicine and Rehabilitation, and the Board of Thoracic Surgery; or
- (3) Recognized by the medical community as a specialist in radiology. Check the American Medical Directory or the Dictionary of Medical Specialist for (1) and (2).

To substantiate (3), the record should show how much of the physician's practice is devoted to radiology as well as what other specialties he/*she* practices, and the basis for recognition as a specialist by the medical community; i.e., do other physicians regularly refer radiology work to him/*her*, and does he/*she* have arrangements with local hospitals to provide radiology services or acts as a radiology consultant.

H0018

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.102(a) Standard - Physician Supervision

The performance of the roentgenologic procedures is subject to the supervision of a physician who meets the requirements of paragraph (b) of this section and one of the following requirements is met:

- (1) The supervising physician owns the equipment and it is operated only by his employees, or***

- (2) The supervising physician certifies annually that he periodically checks the procedural manuals and observes the operators' performance, that he has verified that equipment and personnel meet applicable Federal, State, and local licensure and registration requirements and that safe operating procedures are used.*
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H0019

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.102(b) Standard - Qualifications of the Physician Supervisor.

Portable X-ray services are provided under the supervision of a licensed doctor of medicine or licensed doctor of osteopathy who is qualified by advanced training and experience in the use of X-rays for diagnostic purposes, i.e., he

- (1) is certified in radiology by the American Board of Radiology or by the American Osteopathic Board of Radiology or possesses qualifications which are equivalent to those required for such certification, or*
 - (2) is certified or meets the requirements for certification in a medical specialty in which he has become qualified by experience and training in the use of X-rays for diagnostic purposes, or*
 - (3) specializes in radiology and is recognized by the medical community as a specialist in radiology.*
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H0020

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104 - Condition for Coverage: Qualifications, Orientation and Health of Technical Personnel.

Portable X-ray services are provided by qualified technologists

Interpretive Guidelines: §486.104

Diplomas, resumes and other records maintained by the supplier or where applicable, in State licensure records, show that a particular academic or training requirement has been met. In the absence of such documentary evidence, request that the individuals involved arrange to have the school or physician involved in attesting to the academic or experience qualifications mail this documentation directly to the SA. Ascertain the

methods of staff member orientation, and also check the procedural manual for content to ensure that it includes all factors cited in the Survey Report.

If a supplier uses the services of a non-physician equipment operator, interview that individual to assess his/her functions, duties, responsibilities and the degree of supervision he/she receives. Review policies and procedures, records of examinations the operator has taken, and reports of inspections of equipment.

H0021

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(a) Standard - Qualifications of Technologists

All operators of the portable X-ray equipment meet the requirements of paragraph (a) (1), (2), or (3) of this section:

- (1) Successful completion of a program of formal training in X-ray technology of not less than 24 months duration in a school approved by the Council on Education of the American Medical Association or by the American Osteopathic Association, or have earned a bachelor's or associate degree from an accredited college or university.*
 - (2) For those whose training was completed prior to July 1, 1996, but on or after July 1, 1960: Successful completion of 24 full months of training and/or experience under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968.*
 - (3) For those whose training was completed prior to July 1, 1960: Successful completion of 24 full months of training and/or experience of which at least 12 full months were under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968.*
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H0023

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b) Standard - Personnel Orientation

The supplier of portable x-ray services has an orientation program for personnel, based on a procedural manual which is: Available to all members of the staff, incorporates relevant portions of professionally recognized documents, and includes instruction in all of the following:

H0024

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(1)

Precautions to be followed to protect the patient from unnecessary exposure to radiation;

Interpretive Guidelines: § 486.104(b)(1)

The supplier of portable X-ray services must have an orientation program for personnel based on a procedural manual which includes instructions in precautions to be followed to protect the patient from unnecessary radiation.

H0025

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(2)

Precautions to be followed to protect an individual supporting the patient during X-ray procedures from unnecessary exposure to radiation;

Interpretive Guidelines: §486.104(b)(2)

The supplier of portable X-ray services must have an orientation program for personnel based on a procedural manual which includes instructions in precautions to be followed to protect an individual supporting the patient during X-ray procedures from unnecessary exposure to radiation.

H0026

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(3)

Precautions to be followed to protect other individuals in the surrounding environment from exposure to radiation;

Interpretive Guidelines: §486.104(b)(3)

The supplier of portable X-ray services must have an orientation program for personnel based on a procedural manual which includes instructions in precautions to be followed to protect other individuals in the surrounding environment from exposure to radiation.

H0027

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(4)

Precautions to be followed to protect the operator of portable X-ray equipment from unnecessary exposure to radiation;

Interpretive Guidelines: §486.104(b)(4)

The supplier of portable X-ray services must have an orientation program for personnel based on a procedural manual which includes instructions in precautions to be followed to protect the operator of portable x-ray equipment from unnecessary exposure to radiation.

H0028

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(5)

Considerations in determining the area which will receive the primary beam;

Interpretive Guidelines: §486.104(b)(5)

The supplier of portable X-ray services must have an orientation program for personnel based on a procedural manual which includes instructions in considerations for determining the area which will receive the primary beam.

H0029

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(6)

Determination of the time interval at which to check personnel radiation monitors;

Interpretive Guidelines: §486.104(b)(6)

The supplier of portable X-ray services must have an orientation program for personnel based on a procedural manual which includes instructions in determining the time interval at which to check personnel radiation monitors.

H0030

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(7)

Use of the personnel radiation monitor in providing an additional check on safety of equipment;

Interpretive Guidelines: §486.104(b)(7)

The supplier of portable X-ray services must have an orientation program for personnel based on a procedural manual which includes instructions in the use of the personnel radiation monitor for providing an additional check on safety of equipment.

H0031

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(8)

Proper use and maintenance of equipment;

Interpretive Guidelines: §486.104(b)(8)

The supplier of portable X-ray services must have an orientation program for personnel based on a procedural manual which includes instructions in proper use and maintenance of equipment.

H0032

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(9)

Proper maintenance of records;

Interpretive Guidelines: §486.104(b)(9)

The supplier of portable X-ray services must have an orientation program for personnel based on a procedural manual which includes instructions in proper maintenance of records.

H0033

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(10)

Technical problems which may arise and methods of solution;

Interpretive Guidelines: §486.104(b)(10)

The supplier of portable X-ray services must have an orientation program for personnel based on a procedural manual which includes instructions in technical problems which may arise and methods of solution.

H0034

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(11)

Protection against electrical hazards;

Interpretive Guidelines: §486.104(b)(11)

The supplier of portable X-ray services must have an orientation program based on a procedural manual that includes instructions in protection against electrical hazards.

H0035

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(b)(12)

Hazards of excessive exposure to radiation;

Interpretive Guidelines: §486.104(b)(12)

The supplier of portable X-ray services must have an orientation program for personnel based on a procedural manual which includes instructions in hazards of excessive exposure to radiation.

H0036

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.104(c) Standard: Employee Records.

Records are maintained and include evidence that-

- (1) Each employee is qualified for his or her position by means of training and experience; and*
- (2) Employees receive adequate health supervision.*

Interpretive Guidelines: §486.104(c)

- (1) Current employee records must be maintained and include a resume of each employee's training and experience.*
 - (2) Records also must contain evidence of adequate health supervision of employees including records of all illnesses and accidents occurring on duty, as well as results of pre-employment and periodic physical examinations.*
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H0037

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.106 - Condition for Coverage: Referral for Service and Preservation of Records

All portable X-ray services performed for Medicare beneficiaries are ordered by a doctor of medicine or doctor of osteopathy and records are properly preserved.

Interpretive Guidelines: §486.106

The supplier's records showing that X-ray services were ordered in writing by a physician licensed to practice in the State are essential to establish that the standards are met. Follow up within a reasonable period (i.e., 90 days) to recheck the supplier records for compliance with this important standard.

While §486.106 is explicit as to the type of information that is requested, there may be some leeway granted in the initial survey in this area. If all pertinent information has been furnished to the supplier, but was simply not retained or recorded by the supplier the standard may be considered as met. However, inform the supplier of the need in the future to obtain specific data as cited in the regulations. This leeway is to be granted only temporarily, and is not to be interpreted as relaxation of the requirement that all standards must be met. The suppliers patient records should be checked for the information specified in §486.106. If past records are not consistently complete as to the required data, the supplier should be informed of the need to establish a system of record keeping that will conform to the regulations. If it is found that no records have been kept, the supplier should be informed that a recheck will be made in 30 days to insure that it is in compliance with this requirement. The surveyor should inform the supplier of the need for keeping records for a period of at least 2 years, or for the period of time required by State law, whichever is longer.

H0038

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.106(a) Standard - Referral by a Physician

Portable X-ray examinations are performed only on the order of a doctor of medicine or doctor of osteopathy licensed to practice in the State. The supplier's records show that:

- (1) The X-ray test was ordered by a licensed doctor of medicine or doctor of osteopathy, and*
 - (2) Such physician's written, signed order specifies the reason an X-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed; it also includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.*
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H0039

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.106(b) Standard - Records of Examinations Performed

Standard - records of examinations performed. The supplier makes for each patient a record of the date of the X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician, the operator(s) of the portable X-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

H0040

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.106(c) Standard - Preservation of Records

Such reports are maintained for a period of at least 2 years, or for the period of time required by State law for such records (as distinguished from requirements as to the radiograph itself), whichever is longer.

H0042

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.108 Condition for Coverage: Safety Standards.

X-ray examinations are conducted through the use of equipment which is free of unnecessary hazards for patients, personnel, and other persons in the immediate environment, and through operating procedures which provide minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

Interpretive Guidelines: §486.108

Each of the eleven safety standards, if applicable, must be met to find a supplier in compliance. Where a State or local radiation health inspection program conducted a survey within 12 months of the Medicare survey, and such inspection reveals compliance with all applicable safety standards, such State or local investigation will satisfy initial compliance with this regulation. If the State inspection did not completely cover each applicable standard, the inspection report is acceptable only for that portion covered, and the surveyor would be responsible for evaluating the pertinent standards not covered in the previous inspection.

Where deficiencies are found to exist at the time of survey, the supplier should be informed that corrective action is necessary within 30 days and that he/she must submit proof that the correction has been made.

H0043

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.108(a) Standard - Tube Housing and Devices to Restrict the Useful Beam

The tube housing is of diagnostic type. Diaphragms, cones, or adjustable collimators capable of restricting the useful beam to the area of clinical interest, are used and provide the same degree of protection as is required of the housing.

H0044

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.108(b) Standard - Total Filtration

- (1) *The aluminum equivalent of the total filtration in the primary beam is not less than shown in the following table except when contraindicated for a particular diagnostic procedure.*

| <i>Operating kVp</i> | <i>Total filtration (inherent plus added)</i> |
|--------------------------|---|
| <i>Below 50 kVp.....</i> | <i>0.5 millimeters aluminum.</i> |
| <i>50-70 kVp.....</i> | <i>1.5 millimeters aluminum</i> |
| <i>Above 70 kVp.....</i> | <i>2.5 millimeters aluminum</i> |

- (2) *If the filter in the machine is not accessible for examination or the total filtration is unknown, it can be assumed that the requirements are met if the half-value layer is not less than that shown in the following table:*

| <i>Operating kVp</i> | <i>Half-value layer</i> |
|----------------------|---------------------------------|
| <i>50 kVp.....</i> | <i>0.6 millimeters aluminum</i> |
| <i>70 kVp.....</i> | <i>1.6 millimeters aluminum</i> |
| <i>90 kVp.....</i> | <i>2.6 millimeters aluminum</i> |
| <i>100 kVp.....</i> | <i>2.8 millimeters aluminum</i> |
| <i>110 kVp.....</i> | <i>3.0 millimeters aluminum</i> |
| <i>120 kVp.....</i> | <i>3.3 millimeters aluminum</i> |

H0045

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.108(c) Standard - Termination of Exposure

A device is provided to terminate the exposure after a preset time or exposure.

H0046

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.108(d) Standard - Control Panel

The control panel provides a device (usually a millimeter or a means for an audible signal to give positive indication of the production of X-rays whenever the X-ray tube is energized. The control panel indicates appropriate indicators (labelled control settings and/or meters) which show the physical factors (such as kVp, mA, exposure time or whether timing is automatic) used for the exposure.

H0047

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.108(e) Standard - Exposure Control Switch

The exposure control switch is of the dead-man type and is so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.

H0048

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.108(f) Standard - Protection Against Electrical Hazards

Only shockproof equipment is used. All electrical equipment is grounded.

H0049

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

486.108(g) Standard - Mechanical Supporting or Restraining Devices.

Mechanical supporting or restraining devices are provided so that such devices can be used when a patient must be help in position for radiography.

H0050

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.108(h) Standard - Protective Gloves and Aprons

Protective gloves and aprons are provided so that when the patient must be held by an individual, that individual is protected with these shielding devices.

H0051

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.108(i) Standard - Restriction of the Useful Beam

Diaphragms, cones, or adjustable collimators are used to restrict the useful beam to the area of clinical interest.

H0052

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.108(j) Standard - Personnel Monitoring

A device which can be worn to monitor radiation exposure (e.g., a film badge) is provided to each individual who operates portable X-ray equipment. The device is evaluated for radiation exposure to the operator at least monthly and appropriate records are maintained by the supplier of portable X-ray services of radiation exposure measured by such a device for each individual.

H0053

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.108(k) Standard - Personnel and Public Protection.

No individual occupationally exposed to radiation is permitted to hold patients during exposures except during emergencies, nor is any other individual regularly used for this service. Care is taken to assure that pregnant women do not assist in portable X-ray examinations.

H0054

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.110 - Condition for Coverage: Inspection of Equipment

Inspections of all x-ray equipment and shielding are made by qualified individuals at intervals not greater than every 24 months.

Interpretive Guidelines: §486.110

If State records or suppliers records fail to indicate that State or local radiation health inspections have been performed within 24 months of the Medicare survey, the survey for Medicare purposes of the supplier by a qualified inspector will satisfy this requirement, if the surveyor is a qualified inspector.

H0055

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.110(a) Standard - Qualified Inspectors

Inspections are made at least every 24 months by a radiation health specialist who is on the staff of or approved by an appropriate State or local government agency.

H0056

(Rev. 28; Issued: 09-07-07; Effective/Implementation Date: 09-07-07)

§486.110(b) Standard - Records of Inspection and Scope of Inspection

The supplier maintains records of current inspections which may include the extent to which equipment and shielding are in compliance with the safety standards outlined in §486.108.

Transmittals Issued for this Appendix

| Rev # | Issue Date | Subject | Impl Date | CR# |
|------------------------|-------------------|--|------------------|------------|
| R28SOM | 09/07/2007 | Revisions to Appendix D, Guidance to Surveyors for Portable X-ray Services | 09/07/2007 | N/A |
| R01SOM | 05/21/2004 | Initial Release of Pub 100-07 | N/A | N/A |