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Aspen Federal Regulation Set: H 06.01 PORTABLE X-RAY REQUIREMENTS

FED - H0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline

FED - H0005 - COMPLIANCE WITH FED/STATE/LOCAL LAWS

Title COMPLIANCE WITH FED/STATE/LOCAL LAWS

Type Condition

CFR 486.100

Regulation Definition

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

Interpretive Guideline

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, equipment model number, serial number, and date of 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.

FED - H0006 - LICENSURE OR REGISTRATION OF SUPPLIER

Title LICENSURE OR REGISTRATION OF SUPPLIER

Type Standard

CFR 486.100(a)

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Regulation Definition

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:

- licensed or registered pursuant to such law, or
- approved by the agency of the State or locality responsible for licensure or registration as meeting the standards established for such licensure or registration.

Interpretive Guideline

FED - H0007 - LICENSURE OR REGISTRATION OF PERSONNEL

Title LICENSURE OR REGISTRATION OF PERSONNEL

Type Standard

CFR 486.100(b)

Regulation Definition

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

Interpretive Guideline

FED - H0011 - LICENSURE OR REGISTRATION OF EQUIPMENT

Title LICENSURE OR REGISTRATION OF EQUIPMENT

Type Standard

CFR 486.100(c)

Regulation Definition

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.

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FED - H0016 - CONF.W/OTHER FED/STATE/LOCAL LAWS, REGS

Title CONF.W/OTHER FED/STATE/LOCAL LAWS, REGS

Type Standard

CFR 486.100(d)

Regulation Definition

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

Interpretive Guideline

FED - H0017 - SUPERVISION BY A QUALIFIED PHYSICIAN

Title SUPERVISION BY A QUALIFIED PHYSICIAN

Type Condition

CFR 486.102

Regulation Definition

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

Interpretive Guideline

The performance of X-ray tests is subject to the supervision of a physician qualified by advanced training and experience in use of diagnostic X-rays regardless 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, 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 IC.)

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 Specialists for (1) and (2). To substantiate (3), the record should show how much of the physician's practice

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is devoted to radiology as well as what other specialties he practices, and the basis for recognition as a specialist by the medical community; i.e., do other physicians regularly refer radiology work to him, and does he have arrangements with local hospitals to provide radiology services or act as a radiology consultant.

FED - H0018 - PHYSICIAN SUPERVISION

Title PHYSICIAN SUPERVISION

Type Standard

CFR 486.102(a)

Regulation Definition

The performance of the roentgenologic procedures must be subject to the supervision of a physician who meets the requirements of 405.1412(b) and one of the following requirements must be 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.

Interpretive Guideline

FED - H0019 - QUALIFICATIONS OF PHYSICIAN SUPERVISOR

Title QUALIFICATIONS OF PHYSICIAN SUPERVISOR

Type Standard

CFR 486.102(b)

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Regulation Definition

Portable X-ray services must be 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.

Interpretive Guideline

FED - H0020 - QUALIF/ORIENT. TECH PERSONNEL/RECORDS

Title QUALIF/ORIENT. TECH PERSONNEL/RECORDS

Type Condition

CFR 486.104

Regulation Definition

Portable X-ray services are provided by qualified technologists.

Interpretive Guideline

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.

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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 records and reports of inspections of equipment.

FED - H0021 - QUALIFICATIONS OF TECHNOLOGISTS

Title QUALIFICATIONS OF TECHNOLOGISTS

Type Standard

CFR 486.104(a)

Regulation Definition

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

- (1) Successful completion of a program of formal training in X-ray technology at which the operator received appropriate training and demonstrated competence in the use of equipment and administration of portable x-ray procedures; or
- (2) Successful completion of 24 full months of training and experience under the direct supervision of a physician who is certified in radiology or who possesses qualifications which are equivalent to those required for such certification.

Interpretive Guideline

FED - H0023 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Standard

CFR 486.104(b)

Regulation Definition

The supplier of portable X-ray services must have an orientation program for personnel, based on a procedural

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manual which is available to all members of the staff, incorporates relevant portions of professionally recognized documents, and includes specifically required instructions.

FED - H0024 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(1)

Regulation Definition

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 exposure to radiation.

Interpretive Guideline

FED - H0025 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(2)

Regulation Definition

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.

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FED - H0026 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(3)

Regulation Definition

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.

Interpretive Guideline

FED - H0027 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(4)

Regulation Definition

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.

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FED - H0028 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(5)

Regulation Definition

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

Interpretive Guideline

FED - H0029 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(6)

Regulation Definition

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

Interpretive Guideline

FED - H0030 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(7)

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Regulation Definition

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 in providing an additional check on safety of equipment.

Interpretive Guideline

FED - H0031 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(8)

Regulation Definition

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.

Interpretive Guideline

FED - H0032 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(9)

Regulation Definition

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.

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FED - H0033 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(10)

Regulation Definition

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.

Interpretive Guideline

FED - H0034 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(11)

Regulation Definition

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

Interpretive Guideline

FED - H0035 - PERSONNEL ORIENTATION

Title PERSONNEL ORIENTATION

Type Element

CFR 486.104(b)(12)

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Regulation Definition

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.

Interpretive Guideline

FED - H0036 - EMPLOYEE RECORDS

Title EMPLOYEE RECORDS

Type Standard

CFR 486.104(c)

Regulation Definition

Current employee records must be maintained and include a resume of each employee's training and experience. 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 preemployment and periodic physical examinations.

Interpretive Guideline

FED - H0037 - REFERRAL: SERVICE/RECORD PRESERVATION

Title REFERRAL: SERVICE/RECORD PRESERVATION

Type Condition

CFR 486.106

Regulation Definition

All portable X-ray services performed for Medicare beneficiaries are ordered by a physician or a nonphysician practitioner as provided in §410.32(a) of this chapter or by a nonphysician practitioner as provided in §410.32(a)(2) and records are properly preserved.

Interpretive Guideline

The supplier's records showing that X-ray tests 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's records for compliance with this important standard.

While section 405.1414(a)(2) is explicit as to the type of information that is required in a physician's request, there

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may be some leeway granted in 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 supplier's patient records should be checked for the information specified in section 405.1414(b). 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 recordkeeping 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.

FED - H0038 - REFERRAL BY PHYSICIAN or NONPHYSICIAN PRACT

Title REFERRAL BY PHYSICIAN or NONPHYSICIAN PRACT

Type Standard

CFR 486.106(a)

Regulation Definition

§486.106(a) Standard - Referral by a Physician or nonphysician practitioners.

Portable X-ray examinations are performed only on the order of a physician licensed to practice in the State or by a non-physician practitioner acting within the scope of State law. Such non-physician practitioners may be treated the same as physicians treating beneficiaries for the purpose of this paragraph. The supplier's records show that:

- (1) The portable X-ray test was ordered by a physician or a non-physician practitioner acting within the scope of applicable State law; and
- (2) Such physician or non-physician practitioner's written, signed order specifies the reason a portable X-ray test is

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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.

FED - H0039 - RECORDS OF EXAMINATIONS PERFORMED

Title RECORDS OF EXAMINATIONS PERFORMED

Type Standard

CFR 486.106(b)

Regulation Definition

The supplier makes for each patient a record of the date of the portable X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician or nonphysician practitioner, 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.

Interpretive Guideline

FED - H0040 - PRESERVATION OF RECORDS

Title PRESERVATION OF RECORDS

Type Standard

CFR 486.106(c)

Regulation Definition

Reports of portable X-ray examination must be 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.

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FED - H0042 - SAFETY STANDARDS

Title SAFETY STANDARDS

Type Condition

CFR 486.108

Regulation Definition

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 Guideline

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. However, if any equipment, operating procedures, or shielding was noted as constituting a potential hazard, it must be corrected before recommending approval. Also, 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 must submit proof that correction has been made.

FED - H0043 - HOUSING/DEVICES TO RESTRICT USEFUL BEAM

Title HOUSING/DEVICES TO RESTRICT USEFUL BEAM

Type Standard

CFR 486.108(a)

Regulation Definition

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

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FED - H0044 - TOTAL FILTRATION

Title TOTAL FILTRATION

Type Standard

CFR 486.108(b)

Regulation Definition

The aluminum equivalent of the total filtration in the primary beam must be not less than that shown in the following table except when contraindicated for a particular diagnostic procedure:

OPERATING kVp TOTAL FILTRATION (Inherent plus added)

Below 50 kVp 0.5 mm aluminum
50 - 70 kVp 1.5 mm aluminum
Above 70 kVp 2.5 mm aluminum

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:

OPERATING kVp HALF-VALUE LAYER

50 kVp 0.6 mm aluminum
70 kVp 1.6 mm aluminum
90 kVp 2.6 mm aluminum
100 kVp 2.8 mm aluminum
110 kVp 3.0 mm aluminum
120 kVp 3.3 mm aluminum

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FED - H0045 - TERMINATION OF EXPOSURE

Title TERMINATION OF EXPOSURE

Type Standard

CFR 486.108(c)

Regulation Definition

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

Interpretive Guideline

FED - H0046 - CONTROL PANEL

Title CONTROL PANEL

Type Standard

CFR 486.108(d)

Regulation Definition

The control panel must provide a device (usually a milliammeter) 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 includes 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.

Interpretive Guideline

FED - H0047 - EXPOSURE CONTROL SWITCH

Title EXPOSURE CONTROL SWITCH

Type Standard

CFR 486.108(e)

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Regulation Definition

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

Interpretive Guideline

FED - H0048 - PROTECTION AGAINST ELECTRICAL HAZARDS

Title PROTECTION AGAINST ELECTRICAL HAZARDS

Type Standard

CFR 486.108(f)

Regulation Definition

Only shockproof equipment may be used. All electrical equipment must be grounded.

Interpretive Guideline

FED - H0049 - MECHANICAL SUPPORT/RESTRAINING DEVICES

Title MECHANICAL SUPPORT/RESTRAINING DEVICES

Type Standard

CFR 486.108(g)

Regulation Definition

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

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FED - H0050 - PROTECTIVE GLOVES AND APRONS

Title PROTECTIVE GLOVES AND APRONS

Type Standard

CFR 486.108(h)

Regulation Definition

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

Interpretive Guideline

FED - H0051 - RESTRICTION OF THE USEFUL BEAM

Title RESTRICTION OF THE USEFUL BEAM

Type Standard

CFR 486.108(i)

Regulation Definition

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

Interpretive Guideline

FED - H0052 - PERSONNEL MONITORING

Title PERSONNEL MONITORING

Type Standard

CFR 486.108(j)

Regulation Definition

A device which can be worn to monitor radiation exposure (e.g., a film badge) must be provided to each individual who

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operates portable X-ray equipment. The device must be evaluated for radiation exposure to the operator at least monthly and appropriate records must be maintained by the supplier of portable X-ray services of radiation exposure measured by such a device for each individual.

FED - H0053 - PERSONNEL AND PUBLIC PROTECTION

Title PERSONNEL AND PUBLIC PROTECTION

Type Standard

CFR 486.108(k)

Regulation Definition

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

Interpretive Guideline

FED - H0054 - INSPECTION OF EQUIPMENT

Title INSPECTION OF EQUIPMENT

Type Condition

CFR 486.110

Regulation Definition

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

Interpretive Guideline

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.

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FED - H0055 - QUALIFIED INSPECTORS

Title QUALIFIED INSPECTORS

Type Standard

CFR 486.110(a)

Regulation Definition

Inspections must be 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 governmental agency.

Interpretive Guideline

FED - H0056 - RECORDS OF INSPECTION/SCOPE OF INSPECTION

Title RECORDS OF INSPECTION/SCOPE OF INSPECTION

Type Standard

CFR 486.110(b)

Regulation Definition

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

Interpretive Guideline

FED - H9999 - FINAL COMMENTS

Title FINAL COMMENTS

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline