641—37.12(136C) Records.

37.12(1) *General provisions of measurement units.*

a. Each licensee or registrant shall use the special units curie, rad, rem and roentgen, counts per minute (cpm), disintegrations per minute (dpm), or the SI units becquerel, gray, sievert and coulomb per kilogram, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this chapter.

b. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this chapter, such as total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

c. In the records required by this chapter, the licensee may record quantities in SI units in parentheses following each of the units specified in subrule 37.12(1). However, all quantities must be recorded as stated in subrule 37.12(1).

d. Notwithstanding the requirements of subrule 37.12(1), when recording information on shipment manifests, information must be recorded in the International System of Units (SI) or in SI and units as specified in subrule 37.12(1).

e. Notwithstanding the requirements of subrule 37.12(1), records of removable radioactive surface contamination on packages shall be recorded in disintegrations per minute (dpm).

37.12(2) *Record retention of medical images.*

a. Medical images, whether stored digitally or on film, shall be retained for 7 years for patients 18 years of age or older, and for 7 years plus the difference between the patient's age and 18 for minors.

b. Facilities currently using hard-copy film may continue to retain imaging using this method throughout the retention period.

c. Facilities using both digital storage (computer media) and hard-copy storage may continue to retain imaging using both of these methods throughout the retention period. Digital data (computer media) should be backed up, or refreshed, at appropriate intervals as defined by the facility.

d. Facilities solely utilizing digital storage to store study information for which a report is generated must ensure the storage conditions prevent deterioration throughout the retention period required. The facility must maintain either retrieval or access or both to the stored images.

e. Facilities that have identified medical images as being involved in a legal case should immediately code the images appropriately and retain them for the required retention period defined in this paragraph or longer if required by the facility's internal policies or procedures. At the end of the retention period, the facility should follow its internal procedures and consult appropriate internal personnel for further disposition instructions as defined by the facility.

f. If records are temporarily transferred to any party, the facility should maintain appropriate information relating to location, date of release, and individual having custody of the records.

g. A facility that is ceasing operations must either transfer its medical image records to another facility or provide the records to its patients. The facility must send a certified letter as to the location, or disposition, of the records to notify the patients of the transferal.

h. Facilities performing mammography shall maintain mammography records in accordance with the requirements of 641—Chapter 41 and the requirements of this chapter. The retention period shall be the longer of the two durations specified, which is a minimum of seven years.

37.12(3) *Records of radiation protection programs.*

a. Each licensee or registrant shall maintain records of the radiation protection program, including:

(1) The provisions of the program; and

(2) Audits and other reviews of program content and implementation.

b. The licensee or registrant shall retain the records required by this rule until the department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by subrule 37.12(1) for three years after the record is made.

37.12(4) *Records of surveys.*

a. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by subrule 37.11(13). The licensee or registrant shall retain these records for three years after the record is made.

b. The licensee or registrant shall retain each of the following records until the department terminates each pertinent license or registration requiring the record:

(1) Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

(3) Records showing the results of air sampling, surveys, and bioassays; and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records required in subrule 37.12(4) or shall make provisions with the department for transfer to the department.

37.12(5) *Records of tests for leakage or contamination of sealed sources.* Records of tests for leakage or contamination of sealed sources shall be kept in units of microcurie or becquerel and maintained for inspection by the department for five years after the records are made.

37.12(6) *Records of prior occupational dose.*

a. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in subrule 37.11(7) until the department terminates each pertinent license or registration requiring this record.

b. The licensee or registrant shall retain records used in preparing the record required in subrule 37.12(6) for three years after the record is made.

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records required in subrule 37.12(2) or shall make provisions with the department for transfer to the department.

37.12(7) *Records of planned special exposures.*

a. For each use of the provisions of subrule 37.12(7) for planned special exposures, the licensee or registrant shall maintain records that describe:

(1) The exceptional circumstances requiring the use of a planned special exposure;

(2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization;

(3) What actions were necessary;

(4) Why the actions were necessary;

(5) What precautions were taken to ensure that doses were maintained ALARA;

(6) What individual and collective doses were expected to result; and

(7) The doses actually received in the planned special exposure.

b. The records shall be retained until the department terminates each pertinent license or registration requiring these records.

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records required in subrule 37.12(7) or shall make provisions with the department for transfer to the department.

37.12(8) *Records of individual monitoring results.*

a. Recordkeeping requirements. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to subrule 37.11(14) and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect on or before January 1, 1994, need not be changed. These records shall include all of the following, when applicable:

(1) The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

(2) The estimated intake of radionuclides set forth in subrule 37.11(14);

(3) The committed effective dose equivalent assigned to the intake of radionuclides;

(4) The specific information used to calculate the committed effective dose equivalent pursuant to paragraph 37.11(6)*"c"*;

(5) The total effective dose equivalent when required by subrule 37.11(4);

(6) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

b. Recordkeeping frequency. The licensee or registrant shall make entries of the records specified in subrule 37.12(2) at intervals not to exceed one year.

c. Recordkeeping format. The licensee or registrant shall maintain the records specified in paragraph 37.12(8)*"a"* in clear and legible form.

d. Embryo or fetus records. The licensee or registrant shall maintain the records of dose to an embryo or fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file but may be maintained separately from the dose records.

e. Retention during license or registration. The licensee or registrant shall retain each required form or record until the department terminates each pertinent license or registration requiring the record.

f. Retention after termination. Upon termination of the license or registration, the licensee or registrant shall permanently store records required in this rule or shall make provision with the department for transfer to the department.

37.12(9) *Records of dose to individual members of the public.*

a. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public as set forth in subrule 37.11(3).

b. The licensee or registrant shall retain the records required by this rule until the department terminates each pertinent license or registration requiring the record.

37.12(10) *Records of waste disposal.*

a. Each licensee shall maintain records of the disposal of licensed materials and disposal or burial in soil.

b. The licensee shall retain the records until the department terminates each pertinent license or registration requiring the record.

37.12(11) *Records of testing entry control devices for very high radiation areas.*

a. Each licensee or registrant shall maintain records of tests made pursuant to subrule 37.11(17) on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

b. The licensee or registrant shall retain the records for three years after the record is made.

37.12(12) *Form of records.*

a. Each record required by this chapter shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period, or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

b. The licensee or registrant shall retain the records required by this chapter until the department terminates each pertinent license or registration requiring the record.

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