

75198 Record Keeping

(a)

All records, forms, and notices required by this Article shall be maintained in a secure location(s) at the dialysis facility. (1) Access to documentation shall be restricted to authorized dialysis facility personnel except where otherwise noted in this Article or as required by law. (2) Documentation shall be made available to departmental representatives for inspection and copying.

(1)

Access to documentation shall be restricted to authorized dialysis facility personnel except where otherwise noted in this Article or as required by law.

(2)

Documentation shall be made available to departmental representatives for inspection and copying.

(b)

Prior to reprocessing dialysis filters, each dialysis facility shall establish and maintain records which include: (1) A Procedure Record which includes the methods and procedures used at the dialysis facility for cleaning, disinfecting and storing, performance testing including pass/fail criteria, and disinfectant rinsing of the hemodialyzer. (2) A Training Record which includes the tasks assigned to each technician involved in the reprocessing of hemodialyzers, a description of the type of training and/or education required for each task, and written

verification by the person responsible for training that such training has been received. (3) An Equipment Record for all equipment utilized in reprocessing, including the water and air quality control systems, which includes maintenance schedules, procedures, tests, and test results. (4) An Audit Record including quality assurance audit procedures and results. (5) A Device History Record to be maintained for a period of six months after the last reprocessing of the dialyzer which includes, but is not limited to, the following information: (A) Patient's name (last name, first name or initial) (B) Dates of dialysis treatment (C) Dates of disinfectant rinsing (D) Dialyzer type and model (E) Reuse number (F) Results of any performance test (G) Initials or other identification of the reprocessing technician (H) Comments on the reason for dialyzer failure and, if necessary, subsequent dialyzer acceptance

(1)

A Procedure Record which includes the methods and procedures used at the dialysis facility for cleaning, disinfecting and storing, performance testing including pass/fail criteria, and disinfectant rinsing of the hemodialyzer.

(2)

A Training Record which includes the tasks assigned to each technician involved in the reprocessing of hemodialyzers, a description of the type of training and/or education required for each task, and written verification by the person responsible for training that such training has been received.

(3)

An Equipment Record for all equipment utilized in reprocessing, including the water and air quality control systems, which includes maintenance schedules, procedures, tests, and test results.

(4)

An Audit Record including quality assurance audit procedures and results.

(5)

A Device History Record to be maintained for a period of six months after the last reprocessing of the dialyzer which includes, but is not limited to, the following information: (A) Patient's name (last name, first name or initial) (B) Dates of dialysis treatment (C) Dates of disinfectant rinsing (D) Dialyzer type and model (E) Reuse number (F) Results of any performance test (G) Initials or other identification of the reprocessing technician (H) Comments on the reason for dialyzer failure and, if necessary, subsequent dialyzer acceptance

(A)

Patient's name (last name, first name or initial)

(B)

Dates of dialysis treatment

(C)

Dates of disinfectant rinsing

(D)

Dialyzer type and model

(E)

Reuse number

(F)

Results of any performance test

(G)

Initials or other identification of the reprocessing technician

(H)

Comments on the reason for dialyzer failure and, if necessary, subsequent dialyzer acceptance

(c)

Each record as required in this section shall bear the signature or other identification of the person responsible for implementing the requirements of the record.

(d)

Prior to implementing a procedure change to any record, the change shall be authorized in writing by the person responsible for implementing the requirements of the record or the facility medical director.