no purpose is served by retaining HHE on the Table. Removing HHE as a Table injury places the burden of proof on the petitioner that an HHE was caused by a vaccine and that it resulted in death or residual effects lasting at least 6 months.

Additional comments were received in response to the Notice published on March 24, 1994, requesting comments on the Miller study and 1994 IOM report. Two commenters argued that the conclusions of this IOM report are inconsistent with the Department's proposal to remove HHE from the Vaccine Injury Table. The commenters suggested that because the Qualifications and Aids to Interpretation include ''loss of consciousness'' as one of the symptoms of HHE, and because the NCES would have included a severe shock-collapse resulting in hospitalization as a serious, acute neurologic illness, it is appropriate for HHE to continue to receive the presumption of causation conferred by the Table.

It is important to understand that the Miller study did not purport to set forth a definition of ''encephalopathy'' for purposes of the VICP or the Vaccine Injury Table. Rather, it simply defined a set of conditions which fell under the rubric of ''acute neurologic illness'' that could be studied in relation to the administration of DTP vaccine. Loss of consciousness is not a recognized sign of HHE (see Cody et al.), notwithstanding its inclusion in the original statutory Qualifications and Aids to Interpretation. The Department recognizes that the 1991 IOM Report included among the symptoms of HHE a loss of consciousness. However, the Department believes that this simply reflected some of the case reports in the literature that were reviewed by the IOM. Given the IOM's statement that the cases reported may include other conditions, such as anaphylaxis, the Department does not view the IOM's discussion as a sufficient basis to expand its view of what properly constitutes HHE. *See* 1991 IOM Report, p. 171–177. Rather, children experiencing a loss of consciousness should properly be considered under the rubric of encephalopathy. Furthermore, there is no clear evidence that HHE (1) represents acute neurologic dysfunction, (2) requires medical intervention (although medical consultation is frequently sought), or (3) leads to any permanent sequelae or death. It is unlikely that nay of the cases described in the NCES were those of infants experiencing HHE. In light of these considerations, the Department concludes that there is an insufficient basis to retain HHE as a separate category on the Table.

Residual Seizure Disorder

One commenter suggested that some of the seizure classifications under Residual Seizure Disorder are out of date. They cited the example of ''grand mal'' seizures which has been dropped from the International Classification of Diseases. The commenter also questioned the use of the word ''signs'' in this section. The Department agrees with the commenter that some of the original seizure terminology has changed over time. Section 100.3(b)(4) has been revised and the word ''signs'' has been deleted from the text.

One commenter objected to proposed paragraph (b)(3)(ii) regarding the 24-hour requirement for separation of seizures under Residual Seizure Disorder. The commenter disagreed that a 24-hour separation in seizures makes the diagnosis of recurrent seizures (epilepsy) more likely, and that seizures occurring on the same day are generally regarded as part of the same event.

The Department intends that the 24-hour requirement for the separation of seizures will make it more likely that a Petitioner who qualifies under Residual Seizure Disorder has a recurring seizure disorder (epilepsy). The study cited in the NPRM, (Reference: Hauser WA. et al: Seizure recurrence after a first unprovoked seizure. NEJM 1982; 307(9):522–528), shows that seizures separated by more that 24 hours make a recurrent disorder more likely. Its importance is underscored by the fact that seizures commonly occur in clusters. For purposes of predicting recurrence of seizures, those occurring within a 24-hour period are generally viewed as a single event (with the same cause). It is likely that any petitioner who experiences a vaccine-related epileptic disorder will still qualify by having further seizures over the 12-month period specified under the statute. See section 2114(b)(2)(A) of the Act.

Recognizing the commenter's concerns, and in the interest of clarity, the Department has modified slightly the definition of a distinct seizure episode for purposes of this section. The last sentence of § 100.3(b)(3)(i) now reads, ''A distinct seizure or convulsion episode is ordinarily defined as including all seizure or convulsive activity occurring within a 24-hour period, unless competent and qualified expert neurologic testimony is presented to the contrary in a particular case.''

Two commenters did not agree with the language in paragraph (b)(4) that absence (petit mal) epilepsy is not associated with acute encephalopathy secondary to DTP immunization. Both suggested that the diagnosis be determined by requiring such a child to have an EEG with 3-per-second spike-and-wave, since it is known that children who have such minor seizures with different EEG's are often the victims of severe brain damage and should not be excluded. Finally, it was suggested that the phrase ''if properly diagnosed'' be used under these conditions. The Department's response to these comments is as follows.

There is little credible evidence to support the conclusion that absence (petit mal) epilepsy is associated with acute encephalopathy following vaccination. It is true, however, that atypical absence and other forms of spike-and-wave epilepsy may be the sequelae of an acute encephalophathy, but are not in themselves the features of such. Following acute encephalopathy, features of atypical absence seizures may develop months to years later as part of the sequelae to the acute injury. Other types of staring behavior may constitute seizure activity associated with an acute encephalopathy, such as an individual with Herpes simplex type 1 encephalitis. However, these patients typically present with other clinical signs of acute encephalopathy. (Generalized Seizures: Absence. In Dreifuss F. (ed): Pediatric Epileptology. Boston, J. Wright/PSG, 1983, p. 65–91.) It also should be noted that seizures alone do not constitute an encephalopathy. (1991 IOM Report, page 87).

Requiring EEG confirmation of 3-per-second spike-and-wave to make the diagnosis of absence (petit) epilepsy may be excessively restrictive. While patients may have these characteristic EEG findings, it is neither practical nor advisable to require that the EEG constitute the basis for diagnosis. Frequently, absence (petit mal) epilepsy is diagnosed on clinical criteria alone, (i.e., expected age group, seizure behavior, relationship to hyperventilation and/or response to ethosuximide therapy). It is therefore impractical to require EEG confirmation. Furthermore, inserting the phrase ''if properly diagnosed'' would create confusion as to whether EEG confirmation is necessary for the diagnosis of this condition.

One commenter suggested it is incorrect to state that petit mal and absence seizures are the only types of seizure activity with which staring can be associated. The Department agrees, and did not intend to imply such in the Preamble to the NPRM. Other