following the acute event. Because testing criteria and the interpretation of results may vary with age group and medical condition, no additional criteria are suggested for the diagnosis of chronic encephalopathy. The Department agrees, however, that the Aids to Interpretation should contain a clear distinction between acute and chronic encephalopathy. As explained above, additional language has been added in the final rule for clarification.

Members of the ACCV suggested the phrase ''return to a normal neurological state'' was too vague, and failed to specify the methods to be used for gauging a ''normal neurological state.'' These members also suggested that there might not be any evidence in the medical records to document this fact. The Department has considered this suggestion, but has determined that the language in the definition of chronic encephalopathy need not be changed. It is the Department's intent that if all other parts of the definition are satisfied, the presumption remains intact unless there is affirmative evidence that the child returned to a normal neurological state; such evidence could consist of documented subjective descriptions of the child's behavior and development and/or objective findings on physical examinations performed by physicians in the post-immunization period. Thus, in those cases where this issue is unclear, or not documented, the presumption would be that a child whose acute encephalopathy was followed by signs of a persistent neurologic deficit did not return to a normal neurological state.

During the June 1–2, 1994 meeting, members of the ACCV also suggested that parts of the definition of encephalopathy in the Qualifications and Aids to Interpretation as published in the NPRM were too restrictive. Specifically, they took issue with the underlined phrase of the introductory language of § 100.3(b)(2)(i)(D), which states that ''[t]he following clinical features alone, or in combination, do not qualify as evidence of an acute encephalopathy or a significant change in either mental status or level of consciousness as described above * * *.'' The Department agrees with the commenters and notes that this language did not reflect accurately the Department's intent. The point of this language as written in the NPRM was further to clarify the language as written in the NPRM was further to clarify the language in the statute, which states that certain signs and symptoms are compatible with an encephalopathy but ''in and of themselves are not conclusive evidence of encephalopathy.'' 42 U.S.C. 300aa–14(b)(3)(A). The language in the statute has been interpreted in many different ways by the Special Masters and has led to results in some cases which the Department believes are inconsistent with the medical and scientific literature on this topic. The medical evidence indicates that certain symptoms do not conclusively establish an encephalopathy, but instead are merely symptoms that are compatible with an encephalopathy. Nevertheless, in order to take account of the concerns of the ACCV, the Department has changed the underlined language above to ''do not demonstrate.''

One commenter suggested that DTP may aggravate pre-existing genetic or congenital conditions, and for that matter, other acquired conditions.

The Department is aware that, in rare instances, a vaccine may alter the clinical course of a pre-existing condition. Under section 2111(c)(1)(C) of the Act, ''significant aggravation'' of a pre-existing condition may establish eligibility for compensation provided the Petitioner is able to demonstrate that a Table injury occurred and that the prior condition was significantly aggravated during the Table timeframe, or is able to demonstrate proof of causation in fact.

In considering the comment, the Department realized that there could be confusion regarding the issue of significant aggravation of pre-existing conditions. Accordingly, the Department decided to eliminate the proposed § 100.3(b)(2)(v). Because the statute includes a definition of ''significant aggravation,'' it is unnecessary for this term to be defined in the final rule. See 42 U.S.C. 300aa–33; section 2133 of Act.

As noted above, the Department received five comments in response to the March 24, 1994, **Federal Register** notice soliciting comments regarding the 1994 IOM report. Two comments, one submitted by the American Academy of Pediatrics, and the other by a vaccine manufacturer, expressed support for the revised Vaccine Injury Table as presented in the NPRM. The commenters stated that further revisions to the proposed Vaccine Injury Table are not warranted based on the conclusions of the latest IOM review. The Academy of Pediatrics did suggest, however, that the Table should reflect the ''possibility that in some children with acute encephalopathy, chronic dysfunction may subsequently exist, but this is a rare event and the data do not allow confirmation or rejection of whether this is a direct association.''

The final rule reflects the concern articulated by the Academy. The revised Table confers a presumption of causation on those individuals who suffer an acute encephalopathy within 3 days after vaccine administration, and who then go on to exhibit 6 months of residual effects, followed by chronic neurological dysfunction.

The other three comments are discussed, where relevant, under the heading ''The Department's Interpretation of the IOM Report.''

Hypotonic-Hyporesponsive Episode (HHE)

One commenter supported the removal of hypotonic-hyporesponsive episode (HHE) from the original Table as proposed by stating that HHE has no long-term effects and does not lead to death; the remaining commenters were critical of the change. One commenter pointed out that HHE is a heterogeneous term, which includes features of HHE and anaphylaxis. It also includes a subset of children with ''unusual shock-like states'' who have a ''lot-dependent, bimodal, or other form of onset.'' It was suggested that the Department should give the benefit of doubt in terms of causation to this group. One commenter suggested features of collapse are life-threatening. The Department responds as follows.

Although HHE is not well understood, there are consistent, albeit rare, clinical signs reported to occur transiently following DTP immunization. The onset in young infants is usually within 12 hours following pertussis immunization. Clinical features include pallor, fever, and decreased activity and responsiveness. Although these infants may have a significantly decreased activity level and ''shock-like'' appearance, actual loss of consciousness and hypotension (shock) have not been demonstrated to occur. Disorders such as anaphylaxis should easily be distinguishable from shock-collapse or HHE because of the clearly defined physiologic changes known to occur with anaphylaxis, which do not occur in HHE. See 1991 IOM Report, 171–186; Cody CL, Baraff LJ, Cherry JD, March SM, Manclark CR. 1981. Nature and rates of adverse reactions associated with DTP and DT immunizations in infants and children. Pediatrics 68:650–660.

The 1991 IOM report found evidence ''consistent with a causal relation'' between the pertussis vaccine and HHE (shock collapse), but concluded there was insufficient evidence concerning chronic neurologic damage. Because there is no proven relationship between HHE and residual neurologic damage,