

Dated: July 18, 2003.

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Approved: July 22, 2003.

**Tommy G. Thompson,**

*Secretary.*

■ For the reasons stated above, the Department of Health and Human

Services adds to Subchapter J of Chapter I of Title 42 CFR, a new part 102 to read as follows:

## **PART 102—SMALLPOX COMPENSATION PROGRAM**

Sec.

102.1–102.20. [Reserved]

102.21 Smallpox (Vaccinia) Vaccine Injury Table.

**Authority:** Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 263 of the PHS Act, as amended, Public Law No. 108–20, 117 Stat. 638.

### **§102.21 Smallpox (Vaccinia) Vaccine Injury Table.**

#### **(a) SMALLPOX (VACCINIA) VACCINE INJURY TABLE**

Injury (illness, disability, injury, or condition)	Time interval for first symptom or manifestation of onset of injury after: (1) administration of smallpox (vaccinia) vaccine in recipients (R); or (2) exposure to vaccinia in contacts (C)
1. Significant Local Skin Reaction .....	R or C: 1–21 days.
2. Stevens-Johnson Syndrome .....	R or C: 1–21 days.
3. Inadvertent Inoculation .....	R or C: 1–21 days.
4. Generalized Vaccinia .....	R or C: 1–21 days.
5. Eczema Vaccinatum .....	R or C: 1–21 days.
6. Progressive Vaccinia .....	R or C: 1–21 days.
7. Postvaccinial Encephalopathy, Encephalitis or Encephalomyelitis .....	R or C: 1–21 days.
8. Fetal Vaccinia .....	Maternal R or C: any time in gestation until 7 days after birth.
9. Secondary Infection .....	R or C: 0–30 days.
10. Anaphylaxis or Anaphylactic Shock .....	R: 0–4 hours. C: Not Covered.
11. Vaccinial Myocarditis, Pericarditis, or Myopericarditis .....	R or C: 1–21 days.
12. Death resulting from an injury referred to above in which the injury arose within the time interval referred to above (except as specifically provided in specified paragraph (b) of this section).	R or C: No time interval specified.

#### **(b) Table Definitions and Requirements**

The Table Definitions that follow shall apply to, define and describe the scope of, and be read in conjunction with paragraph (a) of this section.

##### **(1) Significant local skin reaction.—(i)**

**Definition.** Significant local skin reaction is, for purposes of the Table, an unexpected and extreme response at the vaccination or inoculation site that results in a significant scar that is serious enough to require surgical intervention. The onset of this injury is the initial skin lesion at the vaccination or inoculation site that generally occurs with smallpox vaccinations or inoculations. Minor scarring or minor local reactions do not constitute a Table injury. Even a robust take, defined as an area of redness at the vaccination site that exceeds 7.5 cm in diameter with associated swelling, warmth and pain, in general is considered an expected response to the vaccination or inoculation. A robust take does not in itself constitute a Table injury, even when the redness and swelling involves the entire upper arm with associated enlargement and tenderness of the glands (lymph nodes) in the underarm (axilla).

**(ii) Table requirements.** A Table injury for a significant local skin reaction in a recipient or contact

requires sufficient evidence in the medical records of the occurrence of a significant local skin reaction at the vaccination or inoculation site and a permanent, disfiguring scar that resulted from the significant local skin reaction. The scar must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records.

**(2) Stevens-Johnson Syndrome (SJS).—(i) Definition.** SJS (sometimes called erythema multiforme major) is an acute hypersensitivity reaction that affects skin, mucous membranes, and sometimes internal organs (systemic toxicity). For purposes of the Table, both skin and mucous membrane rash or lesions must be present and the rash or lesions may not cover less than ten percent of body surface area. In SJS, mucosal involvement generally predominates. Mucosal lesions generally occur at more than one location and manifest as painful lesions in sites such as the mouth or eyes. Skin rash or lesions in SJS usually consist of red raised areas (erythematous macules), blisters, and ulcerations.

**(ii) Table requirements.** A Table injury for SJS in a recipient or contact requires sufficient evidence in the

medical records of the occurrence of SJS. The SJS, or related complications, must be of sufficient severity to require inpatient hospitalization.

**(3) Inadvertent Inoculation (II).—(i) Definition.** II is the spread of vaccinia virus from an existing vaccination or inoculation site to a second location usually by scratching the vaccination or inoculation site and subsequently spreading the virus, which produces a new vaccinial lesion on the same person. Alternatively, II is the spread of vaccinia virus from an existing vaccination or inoculation site to another person usually by scratching an existing vaccination or inoculation site and subsequently spreading the virus, resulting in a contact case.

**(ii) Table requirements.** A Table injury for II in a recipient or contact requires sufficient evidence in the medical records of the occurrence of II and the occurrence of one of the following:

(A) Eye lesions, e.g., vaccinial keratitis or vaccinial blepharitis, that resulted from II and that led to a permanent sequela, e.g., decrease in visual acuity;

(B) Permanent and disfiguring scar(s) that resulted from II. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g.,