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the Secretary determines that a smallpox vaccine recipient or vaccinia contact died as the direct result of a covered injury (or injuries), his or her survivor(s) may be eligible for death benefits.

(b) *Survivors who may be eligible to receive benefits and order of priority for benefits.*

(1) The Act uses the same categories of survivors and order of priority for benefits as established and defined by the PSOB Program, except as provided in paragraphs (b)(3), (b)(4), and (b)(5) of this section.

(2) The PSOB Program's categories of survivors (known in the PSOB Program as beneficiaries) and order of priority for receipt of death benefits are detailed under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 *et seq.*), as amended, as implemented in 28 CFR Part 32, as amended.

(3) In the PSOB Program, the person who is survived must satisfy the eligibility requirements for a deceased public safety officer, whereas the person who is survived under this Program must be a deceased smallpox vaccine recipient or vaccinia contact who would otherwise have been eligible under this part.

(4) Unlike the PSOB Program, if there are no survivors eligible to receive death benefits under the PSOB Program (as set forth in paragraph (b)(2) of this section), the legal guardian of a deceased minor who was a smallpox vaccine recipient or vaccinia contact may be eligible as a survivor under this Program. Such legal guardianship must be determined by a court of competent jurisdiction under applicable State law.

(5) A surviving dependent younger than the age of 18 whose legal guardian opts to receive a death benefit under the alternative calculation on the dependent's behalf will have the same priority as surviving eligible children under the PSOB Program (consistent with paragraph (b)(2) of this section) even if the dependent is not the surviving eligible child of the deceased person for purposes of the PSOB Program. However, such a dependent may only be eligible to receive benefits under the alternative death benefits calculation, described in § 102.82(d), and is not eligible to receive death benefits under the standard calculation described in § 102.82(c). Because death benefits paid under the alternative calculation will be paid to the dependents' legal guardian(s) on behalf of all such dependents, the Secretary will not divide or apportion such benefits among the dependents.

(6) Any change in the order of priority of survivors or of the eligible category of survivors under the PSOB Program shall apply to requesters seeking death benefits under this Program on the effective date of the change, even prior to any corresponding amendment to this part. Such changes will apply to Request Packages pending with the Program on the effective date of the change, as well as to requests filed after that date.

Subpart C—Covered Injuries

§ 102.20 How to establish a covered injury.

(a) *General.* In order to receive benefits under the Program, a requester must submit documentation showing that a covered injury, as described in § 102.3(g), was sustained. A requester can establish that a covered injury was sustained by demonstrating to the Secretary that a Table injury occurred, as described in paragraph (c) of this section. In the alternative, a requester can establish that an injury was actually caused by a covered countermeasure or accidental vaccinia inoculation, as described in paragraph (d) of this section. The Secretary will consider all relevant medical and scientific evidence, such as medical records and documentation submitted by the requester, when determining whether a covered injury was established. In addition, the Secretary may obtain the views of qualified medical experts in making determinations concerning covered injuries. As set forth in the definition of covered countermeasures, if a covered injury is related to the administration of a covered countermeasure, the countermeasure must have been administered to prevent or treat the smallpox disease or to control or treat the adverse effects of vaccinia vaccination or inoculation or

of the administration of another countermeasure. The time periods described in this part for receiving a covered countermeasure (during the effective period of the Declaration) or for vaccinia contracted from accidental vaccinia inoculation (during the effective period of the Declaration or within 30 days after the end of such period) in relation to a covered injury must also be met.

(b) *Minor injuries.* Any injuries that the Secretary deems minor will not be considered covered injuries. Minor injuries include expected and routine responses to the smallpox vaccine, other covered countermeasures, or accidental vaccinia inoculation that are not severe (e.g., minor scarring or minor local reactions, for instance a mild systemic illness with a generalized maculopapular rash that resolves quickly).

(c) *Table injuries.* A requester may establish that a covered injury occurred by demonstrating that a smallpox vaccine recipient or vaccinia contact sustained an injury listed on the Smallpox (Vaccinia) Vaccine Injury Table, set forth in § 120.21, within the time interval listed on the Table and as defined by the Table's Definitions and Requirements, set forth in § 120.21(b). In such circumstances, the requester need not demonstrate the cause of the injury because the Secretary will presume, only for purposes of making determinations under this subpart, that the injury was the direct result of the administration of a smallpox vaccine or exposure to vaccinia. Even if the Table requirements are satisfied, however, an injury will not be considered a covered injury if the Secretary determines, based upon his review of the evidence, that a source other than the smallpox vaccine or exposure to vaccinia more likely than not caused the injury. In such circumstances, the Table presumption will be rebutted.

(d) *Injuries for which causation must be proven.* If an injury is not included on the Table or if a requester is unable to meet all of the Table requirements with respect to an injury included on the Table (e.g., the first symptom or manifestation of onset of the injury within the time interval included on the Table), a requester may establish a covered injury by proving causation. To establish that a covered countermeasure or accidental vaccinia inoculation caused an injury, the requester must demonstrate, by a preponderance of the evidence (more likely than not), that:

(1) In the case of a smallpox vaccine recipient, he or she sustained an injury as the direct result of the administration of a covered countermeasure (including the smallpox vaccine) during the effective period of the Declaration; or

(2) In the case of a vaccinia contact, he or she sustained an injury as the direct result of vaccinia contracted through accidental vaccinia inoculation from a person described in § 102.3(bb)(2) (a person meeting the definition of a smallpox vaccine recipient, except that the person need not sustain a covered injury, or the contact of such a person), and not as the result of receiving a smallpox vaccine. Such vaccinia must have been contracted during the effective period of the Declaration (or within 30 days after the end of such period). The Secretary will consider an injury that resulted from the administration of a covered countermeasure (other than the smallpox vaccine) to be the direct result of vaccinia contracted through accidental vaccinia inoculation if the covered countermeasure was administered as a result of such vaccinia.

[68 FR 70093, Dec. 16, 2003, as amended at 71 FR 29810, May 26, 2006]

§ 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). Please note that these time intervals do not refer to time periods for the date of diagnosis of the injury.
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.