Comprehensive Adverse Events and Potential Risks List (CAEPR) for Sodium Fluoride F 18 Injection (NSC 749126)

The Comprehensive Adverse Event and Potential Risks list (CAEPR) provides a single list of reported and/or potential adverse events (AE) associated with an agent using a uniform presentation of events by body system. In addition to the comprehensive list, a subset, the Specific Protocol Exceptions to Expedited Reporting (SPEER), appears in a separate column and is identified with bold and italicized text. This subset of AEs (SPEER) is a list of events that are protocol specific exceptions to expedited reporting to NCI via AdEERS (except as noted below). Refer to the 'CTEP, NCI Guidelines: Adverse Event Reporting Requirements' http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf for further clarification. Below is the CAEPR for Sodium Fluoride F 18 Injection.

NOTE: Report AEs on the SPEER **ONLY IF** they exceed the grade noted in parentheses next to the AE in the SPEER. If this CAEPR is part of a combination protocol using multiple investigational agents and has an AE listed on different SPEERs, use the lower of the grades to determine if expedited reporting is required.

Version 1.1[1]

Category (Body System)	Adverse Events[2] with Possible Relationship to Sodium Fluoride F 18 Injection (CTCAE 4.0 Term)	Specific Protocol Exceptions to Expedited Reporting (SPEER) (formerly known as ASAEL)
	No AEs reported in human studies[2, 3, 4]	

[1]This table will be updated as the toxicity profile of the agent is revised. Updates will be distributed to all Principal Investigators at the time of revision. The current version can be obtained by contacting PIO@CTEP.NCI.NIH.GOV. Your name, the name of the investigator, the protocol, and the agent should be included in the e-mail.

[2]When Sodium Fluoride F 18 Injection was approved for marketing in 1972, no adverse events were noted in over 400 patient studies reported in the medical literature [FDA, 2000]. In a 1999 review of the published literature, publicly available reference sources and adverse event reporting systems indicated that no adverse events have been reported for Sodium Fluoride F 18 Injection [FDA, 2000].

[3]It is not known whether Sodium Fluoride F 18 Injection can cause fetal harm when administered to a pregnant woman or whether it can affect reproductive capacity. Therefore, Sodium Fluoride F 18 Injection should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus. The effects of Sodium Fluoride F 18 Injection on human breast milk are unknown. Because many drugs are excreted in human milk, caution should be exercised when Sodium Fluoride F 18 Injection is administered to a nursing woman.

[4]The safety and effectiveness of Sodium Fluoride F 18 Injection has not been established in pediatric patients; therefore, prudence suggests limiting exposure in growing children. Carefully selected pediatric use has been reported [Lim 2007]. Like other bone imaging agents, Sodium Fluoride F 18 Injection is known to localize in rapidly growing epiphyses in developing long bones.

Note: As with many IV administered agents, Sodium Fluoride F 18 Injection could cause an allergic reaction that could potentially pose a threat to life (anaphylaxis). This has not been observed to date. Reasonable precautions should be taken, consistent with normal radiologic and clinical facility practice. The patient should be monitored until the Positron-Emission Tomography (PET) procedure is completed, and trained personnel and emergency equipment should be available per facility standards.

For purposes of informed consent regarding reasonably foreseeable risks to subjects in trials utilizing Sodium Fluoride F 18 Injection, the following potential adverse events are considered extremely rare:

- **Injection-related risks that may include infection, or accidental extravasation of the dose that may lead to discomfort, localized pain, or infection.**
- **Risks related to allergic reaction/anaphylaxis that may be life threatening.**

Note: As with all PET imaging agents, Sodium Fluoride F 18 Injection is a radiopharmaceutical that decays with positron emission. As such, it poses an intrinsic radiation exposure risk. However, when administered in accordance with the Investigator's Brochure as a PET imaging agent, this risk is felt to be extremely small. The organ and total body doses associated with Sodium Fluoride F 18 Injection PET imaging are comparable to or lower than those associated with other widely used clinical nuclear medicine procedures.

Note: Sodium Fluoride F 18 Injection in combination with other agents could cause an exacerbation of any adverse event currently known to be caused by the other agent, or the combination may result in events never previously associated with either agent