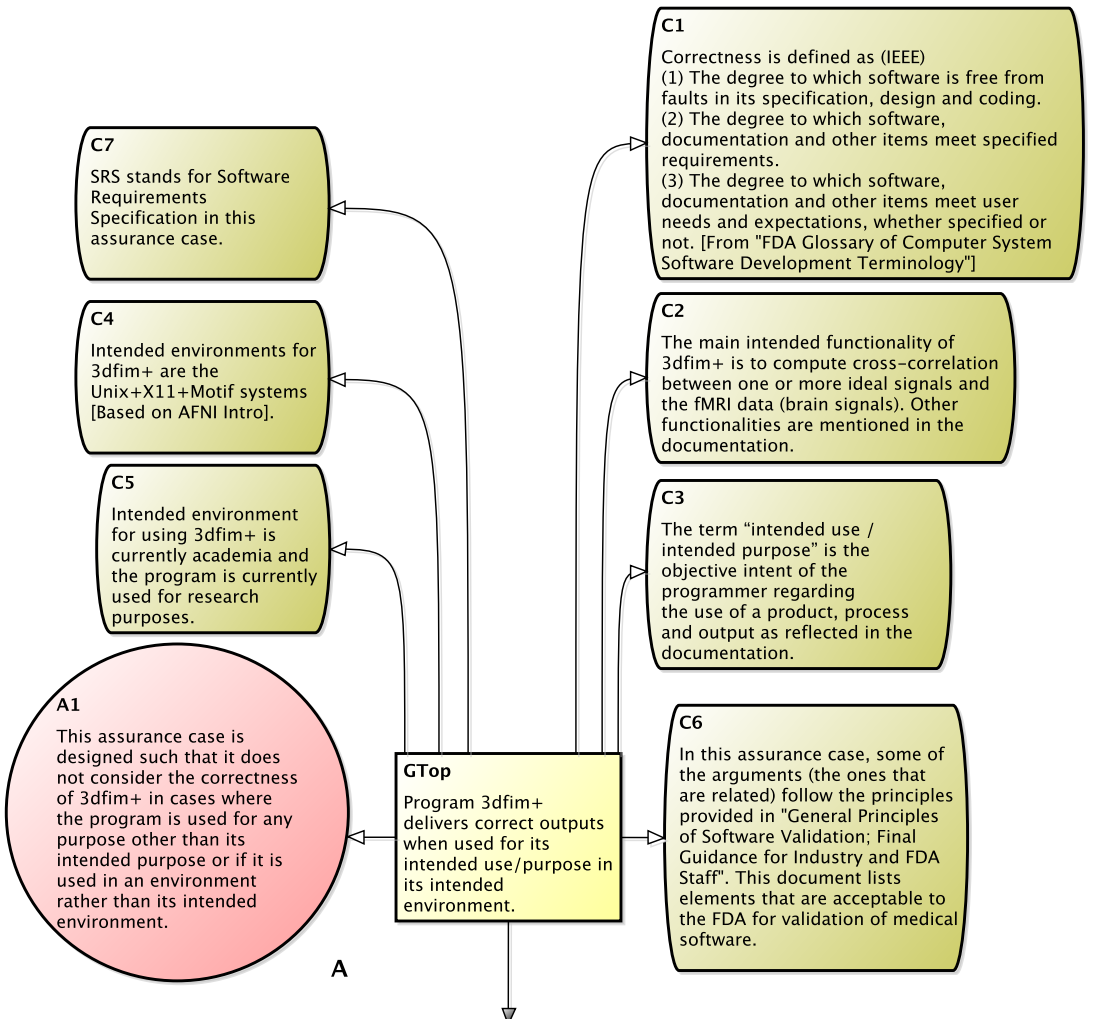
C1
Correctness is defined as (IEEE)
(1) The degree to which software is free from faults in its specification, design and coding.
(2) The degree to which software, documentation and other items meet specified requirements.
(3) The degree to which software, documentation and other items meet user needs and expectations, whether specified or not. [From "FDA Glossary of Computer System Software Development Terminology"]
C7
SRS stands for Software Requirements Specification in this assurance case.
C4
Intended environments for 3dfim+ are the Unix+X11+Motif systems [Based on AFNI Intro].
C2
The main intended functionality of 3dfim+ is to compute cross-correlation between one or more ideal signals and the fMRI data (brain signals). Other functionalities are mentioned in the documentation.
C5
Intended environment for using 3dfim+ is currently academia and the program is currently used for research purposes.
C3
The term “intended use / intended purpose” is the objective intent of the programmer regarding the use of a product, process and output as reflected in the documentation.
A1
This assurance case is designed such that it does not consider the correctness of 3dfim+ in cases where the program is used for any purpose other than its intended purpose or if it is used in an environment rather than its intended environment.
GTop
Program 3dfim+ delivers correct outputs when used for its intended use/purpose in its intended environment.
C6
In this assurance case, some of the arguments (the ones that are related) follow the principles provided in "General Principles of Software Validation; Final Guidance for Industry and FDA Staff". This document lists elements that are acceptable to the FDA for validation of medical software.
A