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are developed within a risk-based framework: the regulatory framework requires the assessment and mitigation of all reasonably foreseeable risks prior to placing the products on the market. A risk assessment includes the determination of key



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hazards, risks, failure modes, and mitigations, for software where the device risks have to be linked to software items.

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Figure 4: Safety Critical Software Development Pyramid Successful creation of safety critical software is dependent on many factors.

Figure 4 illustrates there is a hierarchy of constraint necessary within the development organization. The top of the

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pyramid represents the culture of a safety critical environment.

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how software requirements are  
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(b) The description of the  
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engineering and management.

Secondly, selecting the  
appropriate tools and  
environment for the system.

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Safety-critical system - Wikipedia

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Safety. As part of the total safety and software development program, software cannot be allowed to function independently of the total effort.

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