

VI. PROTECTION OF HUMAN RESEARCH
SUBJECTS

No research on human subjects shall be conducted which could, with reasonable foresight, be expected to jeopardize the life, health, physical integrity, or safety of the subject.

No research procedures shall be undertaken with any ISS crewmember as a human subject without: (1) written approval by the Human Research Multilateral Review Board (HRMRB) and (2) the full written and informed consent of the human subject. Each such approval and consent shall be obtained prior to the initiation of such research, and shall fully comply with the requirements of the HRMRB. The HRMRB is responsible for procedures for initiation of new experiments on-orbit when all consent requirements have been met, but the signature of the human subject cannot be obtained; explicit consent of the human subject will nonetheless be required in all such cases. Subjects volunteering for human research protocols may at their own discretion, and without providing a rationale, withdraw their consent for participation at any time, without prejudice, and without incurring disciplinary action. In addition, approval or consent for any research may be revoked at any time, including after the commencement of the research, by: the HRMRB, the Crew Surgeon, the Flight Director, or the ISS Commander, as appropriate, if the research would endanger the ISS Crew Member or otherwise threaten the mission success. A decision to revoke consent by the human subject or approval by the other entities listed above will be final.

§ 1214.404 Violations.

This subpart is a regulation within the meaning of 18 U.S.C. 799, and whoever willfully violates, attempts to violate, or conspires to violate any provision of this subpart or any order or direction issued under this subpart may be cited for violating title 18 of the U.S. Code and could be fined or imprisoned not more than 1 year, or both.

Subpart 1214.5—Mission Critical Space System Personnel Reliability Program

SOURCE: 55 FR 53289, Dec. 28, 1990, unless otherwise noted.

§ 1214.500 Scope.

This subpart 1214.5 establishes a program designed to ensure that personnel assigned to mission critical positions/

duties meet the screening requirements outlined in § 1214.504 of this part.

§ 1214.501 Applicability.

(a) This regulation applies to civil service and contractor personnel at NASA Headquarters and field installations who work in activities that are vital to the safety and success of mission critical space systems.

(b) The provisions of this regulation apply to all civil service and contractor personnel assigned to mission critical positions/duties with the exception of the personnel addressed in § 1214.501(c) of this part. This includes command and decision making personnel as well as technicians.

(c) This regulation does not include flight crew or payload specialists. They are covered by NASA Management Instruction (NMI) 33304 (14 CFR part 1214, subpart 1214.11), “NASA Astronaut Candidate Recruitment and Selection Program.”

(d) This regulation applies to Space Station Freedom International Partners in that the certification requirements in § 1214.505(f) of this part apply to foreign personnel in mission critical positions/duties.

§ 1214.502 Definitions.

(a) *Mission Critical Space Systems.* The Space Shuttle and other critical space systems, including Space Station Freedom, designated Expendable Launch Vehicles (ELV's), designated payloads, Shuttle Carrier Aircraft and other designated resources that provide access to space. The Director of each NASA Installation will designate areas associated with these systems that are mission critical space systems areas.

(b) *Mission Critical Positions/Duties.* Positions/duties which, if performed in a faulty, negligent, or malicious manner, could jeopardize mission critical space systems and/or delay a mission. While this regulation establishes suitability screening requirements which, if met, will allow unescorted access to mission critical space areas, compliance with the requirements does not authorize unescorted access to classified areas by Personnel Reliability Program (PRP) personnel who do not have security clearances.