

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.

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(c) *Medical Authority.* A NASA civil service or contract physician/psychiatrist responsible for maintaining medical records, providing results of medical evaluations, and interpreting evaluations as they relate to reliable performance of mission-critical duties. The medical authority will coordinate evaluations with the investigatory authority.

(d) *Investigatory Authority.* A NASA civil service or contract individual responsible for reviewing court, law enforcement (Civil, DOD, NASA, other Federal), and other official records and NASA screening plans/procedures records to provide evaluations, recommendations, and guidance to NASA organizations, supervisors, and PRP adjudicators on issuing, denying, or revoking eligibility for mission critical positions/duties.

(e) *Certification.* The determination that an employee assigned to duties as described in §1214.505 of this part, is qualified to perform those duties, and that this employee has been found reliable in accordance with the adjudication guidelines set forth in Attachment B of NMI 8610.13.¹

§ 1214.503 Policy.

(a) The Space Shuttle and the Space Station Freedom are included in the NASA National Resource Protection Program as delineated in NMI 8610.22, "National Resource Protection Program."² The Space Shuttle and the Space Station Freedom provide a capability to support a wide range of scientific applications and commercial, defense, and international uses. Since they will contribute significantly to ensuring a scientifically, technologically, and economically strong and secure nation, program reliability, operational and safety considerations require that stringent measures be taken to provide for the protection of the systems. In addition to the Space Shuttle and the Space Station Freedom, designated ELV's, designated payloads, Shuttle Carrier Aircraft and other designated resources which provide the same critical access to space

¹ Copies may be obtained from NASA Headquarters (Code NA-2), Washington, DC 20546.

² See footnote 1 to §1214.502(e).

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or the ability to accomplish critical objectives in space are considered to constitute valued national resources.

(b) Measures to ensure this protection are:

(1) Special physical security provisions as provided in NMI 8610.22.³

(2) Procedures to ensure that personnel assigned to mission critical positions/duties meet screening requirements, as set forth in §1214.504 of this part prior to unescorted access to areas where mission critical space systems are located.

§ 1214.504 Screening requirements.

(a) Only those persons who are certified under the PRP will have unescorted access to mission critical space systems areas, be assigned to, employed in, or retained in mission critical positions/duties. While this regulation provides for unescorted access to mission critical space systems areas, it does not preclude the need for escorting of PRP personnel who do not have security clearances in classified areas. The certification will be based on an evaluation of screening data which is to be undertaken by a trained evaluator using evaluation guidance and criteria contained in Federal Personnel Manual (FPM) chapter 731 and Attachment B (Adjudication Guidelines) of NMI 8610.13.⁴ The need for impartial and consistent evaluation of data based on a set of standards is considered paramount to the successful implementation of this program.

(b) Determination of suitability for assignment to mission critical positions/duties will be made on the basis of the following criteria:

(1) Supervisory nomination (per requirements of §1214.505(c) of this part) and assurance of ability to perform mission critical duties as evidenced by performance during training and while on the job.

(2) Medical evaluation (for cause only) by NASA designated medical/psychiatric authority consistent with:

(i) The guidelines and requirements of the NASA Occupational Health Division as required to ensure adequate

³ See footnote 1 to §1214.502(e).

⁴ See footnote 1 to §1214.502(e).