NASA Procedural Requirements

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COMPLIANCE IS MANDATORY

Quality Assurance of the NASA Medical Care

Responsible Office: Office of the Chief Health & Medical Officer

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Preface

P.1 Purpose

This NASA Procedural Requirements document (NPR) describes requirements for providing quality assurance in the Agency's medical care system that encompasses both aerospace medicine and occupational health clinical activities and practices. While general principles apply to both occupational health and aerospace medicine practice, the specific administrative processes for each may differ in order to meet the unique needs of the two specialties. This NPR provides the requirements for proper quality assurance in the implementation of both specialties.

P.2 Applicability

This NPR is applicable to NASA Headquarters, NASA Centers, and Component Facilities, as well as to the Jet Propulsion Laboratory and NASA contractors to the extent specified in their contracts.

P.3 Authority

a. 29 U.S.C. 668, Section 19 of the Occupational Safety and Health Act of 1970, as amended, Programs of Federal Agencies.

b. 5 U.S.C. 7901, Health Service Programs.

c. Executive Order 12196, dated February 26, 1980, Occupational Safety and Health Programs for Federal Employees, 3 CFR (1980 Compilation).

d. 29 CFR Part 1960, Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters.

e. NPR 1000.3, The NASA Organization.

f. NPD 1850, NASA Medical System Quality Assurance.

P.4 Applicable Documents

a. NPD 1440.6, NASA Records Management.

b. NPR 1441.1, NASA Records Retention Schedules.

c. NPD 1382.17, NASA Privacy Policy.

d. NPR 1382.1, NASA Privacy Procedural Requirements.

e. NITR 1382.2, NASA Rules and Consequences to Safeguarding PII.

P.5 Measurements/Verification

The Office of the Chief Health and Medical Officer (OCHMO) shall provide assessments/audits of the application of this directive. This will include annual reporting from the Centers of any adverse credentialing or privileging actions, or medical incidents.

P.6 Cancellation

None

/S/ Dr. Richard S. Williams
NASA Chief Health and Medical Officer

Chapter 1. Credentialing and Privileging of Licensed Independent Professionals and Licensed and Non-licensed Support Health-care Personnel

1.1 Introduction

1.1.1 The credentials verification and privileging of health-care staff are necessary for ensuring the competence of all medical practitioners and health-care support personnel permitted to practice medicine by law and organization, and for the safety of employees, patients, and study volunteers.

1.1.2 NASA credentialing and/or privileging criteria described in this NPR shall be required of all NASA civil servants, detailees to NASA, and NASA occupational health contractors who are licensed medical professionals or non-licensed health-care support personnel providing health care for NASA personnel, directed by NASA or under contract to NASA, receiving physician comparability allowance by NASA, or providing health care that is performed at a NASA facility or at an external site.

1.1.3 Health-care delivery is defined as the supervision, monitoring, or direct delivery of prevention, treatment, and management of illness and the preservation of mental and physical well-being through the supervision of, monitoring of, or the direct delivery of services offered by the medical, nursing, and allied health professionals. Health-care providers include licensed independent practitioners (e.g., medical, nursing, and allied health professionals who provide services without direction or supervision). Health-care support personnel include licensed personnel (e.g., nurses, pharmacists, dietitians, and other allied health professionals who provide services with direction or supervision) and non-licensed personnel (e.g., lab and x-ray technicians, emergency medical technicians (EMTs), dental assistants, strength and conditioning specialists, wellness counselors, and other personnel who provide services with direction or supervision).

1.1.4 These policy requirements establish uniform criteria for appointments to the clinical staff, maintenance of clinic privileges, and retention of knowledgeable, experienced, and competent health-care professionals.

1.2 Verification of Credentials

1.2.1 Initial verification and triennial verification of credentials, including primary source verification for all physician practitioners, shall be required of all NASA licensed health-care providers. The core credentialing criteria are:

a. Current state licensure that must be verified with the licensing entity;

b. Relevant education, training, and/or experience (primary source verification is required at the time of initial employment and triennially thereafter);

c. Review by the credentialing official of the National Practitioner Data Bank and other appropriate sources for previous adverse credentialing events. For a NASA non-contractor licensed health-care provider, if any adverse events are noted, the Center will forward the information to the Chief Health

and Medical Officer (CHMO) for determination of action;

d. Current competence; and

e. If not active duty military or U.S. civil servant, evidence substantiating the ability to perform requested privileges.

1.2.2 Initial verification and annual verification of credentials shall be required of all NASA licensed health-care support personnel, including licensed personnel in management roles, and encompasses requirements for licensure, training, and certification. The core credentialing criteria are:

a. Current state licensure that must be verified with the licensing entity;

b. Current Basic Life Support (BLS)/Automated External Defibrillator (AED) training;

c. Current Advanced Cardiac Life Support (ACLS) certification for nurses, EMT-Ps, and pharmacists;

d. Current competence for nurses and EMTs. Baseline competence will be established by the hiring employer during orientation, then competency assessment and training will be accomplished and documented annually; and

e. Current Bloodborne Pathogen training.

1.2.3 Credentialing verification for licensed health-care providers shall be required:

a. Prior to initial appointment and granting of initial clinical privileges;

b. When new privileges are requested; and

c. At triennial renewal of privileges for reappointment which is done in conjunction with that year's performance evaluation.

1.2.4 Some deviation from the core credentialing criteria may be warranted based on the degree of adaptation and customization found in the various health-care activities implemented at each NASA facility.

1.2.5. For the purpose of credentials verification of NASA health-care providers, NASA shall recognize three levels of medical care.

a. Direct patient/client care, counseling, or direct research monitoring shall require both credentials verification and privileging, including:

(1) Evidence of the following credentials - proof of professional education, evidence of specialty training, board certification, if applicable, and current licensure to practice in a U.S. State. If the practitioner is detailed to a NASA Center, licensure to practice in any U.S. State or Territory will be accepted;

(2) When appropriate and based on the individual's function, maintenance of certification in ACLS, Cardiopulmonary Resuscitation (CPR/BLS), and the use of AED and the specific defibrillator(s) in their care location; and

(3) The ability to meet other specific privileging or certification required by the assigned function (e.g., Medical Review Officer (MRO), sigmoidoscopy, stress testing).

b. Practitioners in a supervisory or research monitoring role in a non-direct patient care setting shall require credentials verification and in certain cases privileging, including:

(1) Evidence of the following credentials: proof of professional education, evidence of specialty training, board certification, if applicable, and current licensure to practice in a U.S. State or Territory;

(2) Maintenance of certification in ACLS or CPR/BLS and the use of AED and the specific defibrillator(s) in their care location;

(3) The ability to meet other specific privileging or certification required by the assigned function; and

(4) If functioning as an MRO for NASA, certification by a national certifying agency (e.g., American Association of Medical Review Officers or The Medical Review Officer Certification Council).

c. Physicians who are in management positions and are no longer actively practicing medicine (management positions without direct patient contact) do not require privileging or peer review activities but shall require evidence of the following credentials:

(1) Proof of professional education, evidence of specialty training, board certification, if applicable, and current licensure to practice in a U.S. State. If the practitioner is detailed to a NASA Center, licensure to practice in any U.S. State or Territory will be accepted.

(2) Maintenance of certification in ACLS or CPR/BLS the use of AED and specific defibrillator(s) in their care location.

d. The above stipulations shall not apply to personnel at non-NASA offsite facilities to which employees/patients may be referred.

1.2.6 Current competence for initial clinical privileges for health-care providers shall consist of signed letters of informed opinion from specialty certification boards, peers of personal acquaintance, medical supervisors, academic program directors, or by demonstrated competency documented through peer review activities and outcome monitors that are part of the established medical quality assurance processes and system.

a. A search for any history of medical malpractice and of criminal record shall be conducted, including a query of the National Practitioner's Data Bank and other appropriate sources.

1.2.7 All records containing credentialing information shall be maintained in accordance with 5 U.S.C. 552a; the Privacy Act of 1974, as amended; NPR 1382.1, NASA Privacy Procedural Requirements; and the NASA records retention schedules as specified in NPR 1441.1D.

1.2.8 In the case of civil service personnel, records of health-care providers and support personnel credentials (initial and routine verification) and a list of privileges shall be securely maintained by each Center credentialing office, the clinic in which the practitioner is privileged, or at the point of care.

1.2.9 In the case of onsite contractors, records of health-care providers' credentials verification and a list of privileges shall be maintained and updated by the contractor with copies of the credential files kept at the NASA clinic location.

a. Additionally, relevant licensures shall be provided by health-care providers initially and on license renewal.

1.3 Privileging

1.3.1 Privileging authorizes health-care providers to conduct those clinical tasks for which they must possess adequate skills in order to perform their responsibilities. For health-care support personnel, privileges are delineated by the scope of their licensure and the job description of the position for which they have been hired. Continuing education, relevant training, and skills utilization shall be used to help maintain competence, provide continuous improvement in efficiency, and ensure effectiveness of health care.

1.3.2 Privileges for health-care providers shall be delineated and granted in accordance with documented professional competence, scope of care, and facility support capability for not longer than three years without re-review.

a. For health-care support personnel, competence to continue to perform assigned job duties shall be assessed and documented annually.

1.3.3 Upon request, NASA may privilege incumbent practitioners, who do not meet explicit credentialing criteria, on the basis of their record of experience in a particular setting with demonstrated proficiency in the procedure for which privilege is requested (grandfathering). After licensure verification, each case will be considered individually and decided by the appropriate NASA medical authorities. For licensed independent practitioners, the decision shall be made by the Center Chief Medical Officer (CMO), and for those Centers without a CMO, by the NASA CHMO or designee.

1.3.4 Emergency credentialing and privileges may be transferred from one Center to another in times of emergency or disaster, such as emergent support for natural disasters (e.g., hurricane recovery). A transmittal letter from the NASA Center sending the credentialed providers will be sent to the Office of the Chief Health and Medical Officer (OCHMO) and the receiving institution. This transmittal letter will verify that the providers are licensed, credentialed, and privileged and will specify the estimated amount of time that the providers will be detailed to the receiving NASA Center. The scope and authority to practice will be commensurate with their originating institution.

1.3.5 NASA practitioners in the course of mission support may provide care that extends beyond their NASA Center or Federal property. NASA practitioners who provide patient care at locations of care other than their primary place of practice shall be held to the same standard in regards to credentialing, privileging, and quality of care. The credentialing and privileging will be maintained at their originating facility. For these circumstances, credentials and privileges shall be extended beyond their NASA Center for the purposes of mission and personnel support and include, but are not limited to:

a. Flight surgeons, athletic trainers, nurses, or lab technicians supporting in Star City, Russia;

b. Flight surgeons, athletic trainers, nurses, or lab technicians supporting launch or landing at another NASA Center;

c. Flight surgeons or nursing staff supporting search, rescue, or recovery of astronauts at a location other than a NASA Center;

d. Flight surgeons, athletic trainers, nurses, or lab technicians supporting in Moscow, Russia;

e. Flight surgeons, athletic trainers, nurses, or lab technicians supporting launch or landing of a United States asset on an international partner vehicle in a foreign country; and

f. Flight surgeons or nursing staff supporting aero-medical transport of a patient across international or interstate boundaries.

1.4 Management of Impaired Providers

a. Medical conditions that prevent or reduce a health-care provider's or support personnel's ability to safely execute his or her responsibilities in providing health care shall be considered impairment. Examples of impairment include but are not limited to alcohol or drug impairment, medical condition, severe personal or interpersonal stress or behavioral health disorder. Instances of impairment, or suspected impairment, can be reported by any patient or health-care provider to the appropriate supervisory medical personnel.

b. Health-care providers who may be impaired shall be reviewed by the appropriate supervisory medical personnel to determine if their health status hampers their ability to deliver safe patient care. If the review determines that the condition does affect clinical practice, the health-care provider's privileges may be temporarily held in abeyance, suspended or permanently revoked, and the health-care provider may be removed from all or a portion of their patient care responsibilities.

c. Health-care support personnel who may be impaired shall be reviewed by appropriate personnel from the employing company to determine if their health status hampers their ability to deliver safe patient care. If the review determines that the condition does affect clinical practice, the health-care support personnel's privileges may be temporarily held in abeyance, suspended or permanently revoked, and the health-care support personnel may be removed from all or a portion of their patient care responsibilities according to the employer's policy. Impaired providers in certain licensed disciplines (for example, nurses) must be reported to their licensing board for investigation and intervention.

d. A health-care provider or support personnel may voluntarily restrict their practice when a medical condition interferes with the ability to perform the full scope of duties. In the case of support personnel, concurrence of their supervisor is required.

e. For health-care providers, impairment status shall be reviewed regularly by appropriate medical supervisory personnel (schedule to be determined on a case-by-case basis) to determine when and if any restriction on medical privileges and the ability to perform patient care responsibilities should be suspended, revoked, or changed.

f. Impairment status of support personnel shall be reviewed by the employee's supervisor on a recurring basis to determine when and if any restriction on privileges and the ability to perform patient care responsibilities should be suspended, revoked, or changed.

1.5 Responsibilities

1.5.1 The Chief Health and Medical Officer (CHMO) shall be responsible for:

a. Establishing policy for the credentialing and privileging process for all NASA licensed health-care providers.

b. Ensuring that all NASA medical clinics and organizations appropriately implement the Agency credentialing and privileging process for all NASA licensed health-care providers.

c. Delegating authority to each NASA Center's Chief Medical Officer/Medical Director (where appropriate) to develop a specific credentialing plan and process that:

(1) Ensures an effective credentialing and privileging process for all NASA independent licensed health-care providers;

(2) Provides for granting of medical privileges consistent with these requirements at each NASA Center and facility with a process of triennial review; and

(3) Reviews impaired provider cases to determine when restrictions of clinic privileges should be imposed or rescinded.

d. Reviewing any reported cases of medical incidents or questions of standard of care.

1.5.2 Center Chief Medical Officers/Medical Directors (where appropriate), in collaboration with NASA Center Occupational Health Contracting Officer Technical Representative (COTR) or the appropriate official that serves as that COTR, and in the case of the Johnson Space Center, the Clinical Services Branch Chief, shall be responsible for:

a. Ensuring appropriate medical credentials reviews of all NASA civil service and detailee licensed medical professionals and NASA civil service and detailee non-licensed health-care support personnel and, assuring that the same criteria are stated for health-care providers in all statements of work for contracts procuring health care or human research services;

b. Providing the CHMO with a summary Center credentialing and privileging report on all NASA health-care providers annually;

c. Notifying in writing (e.g., letter and/or e-mail) the CHMO of cases of impaired providers and actions taken as they occur; and

d. Report to the CHMO in writing (e.g., letter and/or e-mail) any medical incidents or questions of medical standard of care.

1.5.3 No individual shall approve or review his/her own credentialing or privileging. The privileging authority for NASA Center CMOs is the CHMO. Privileging authority for contracted Medical Directors at NASA Centers is delegated to contract entities through the mechanism described in section 1.5.2.a.

Chapter 2. Medical Incident Investigation

2.1 Introduction

2.1.1 A Medical Incident is defined as a deviation from the standard of care occurring in the NASA health-care system, as perceived by the patient, another practitioner, or a reviewing quality monitoring body. In addition, any medical incident in which undue harm, illness, morbidity, or mortality or excessive financial burden to the patient or agency occurs as a result of the care provided or omitted shall be cause for review. Such Medical Incidents include, but are not limited to:

a. Missed diagnosis;

b. Incorrect diagnosis;

c. Therapeutic error;

d. Delay of diagnosis and/or treatment;

e. Admissions to a medical facility as a result of delayed diagnosis or treatment;

f. Complication of treatment;

g. Any incident with NASA medical system-wide implications;

h. Any incident in which legal recourse or claims for perceived malpractice or negligence has been brought by the patient or the patient's guardian; and

i. Any incident in which there has been a perceived moral or ethical breach of appropriate practitioner conduct.

2.1.2 Any such incident involving NASA medical care shall be immediately reported, with recommendation for disposition, to the Chief Health and Medical Officer (CHMO) by the Center Chief Medical Officer (CMO) or Medical Director (MD). If the incident involves a CMO or MD, it should be reported directly to the CHMO.

a. Similarly, any adverse trend in clinical performance shall be immediately reported to the CHMO.

b. The CHMO will determine if the reported incident or adverse trend in clinical performance shall be formally investigated to determine cause and possible remedial action.

2.1.3 Medical incident investigations shall be conducted by a provider, or a panel if appropriate, independent to the episode of care or incident, and according to the prescribed procedures established by the CHMO to ensure consistency of review across the Agency (Appendix D). For NASA institutions that act as the primary care providers to their patients, a Quality Assurance/Improvement Committee shall exist to review deviations and conformance to the standard of care, as well as conformance to credentialing and privileging documentation. This panel shall provide the CHMO with a summary of all completed investigations at least quarterly.

2.1.4 Results of a medical incident investigation shall be reported to the CHMO. The CHMO may convene the CMO for appropriate review. This group will be referred to as the Executive Medical Committee. If a CMO served on the original incident review committee, they will not serve on the Executive Medical Committee for that subsequent review.

2.2 Responsibilities

2.2.1 The CHMO shall be responsible for:

a. Determining when a medical incident investigation is warranted and assigning impartial investigating officials as required;

b. Monitoring all medical incident investigations to assure established processes and procedures are followed;

c. Convening the Executive Medical Committee to review the results of medical incident investigations for final response and determination of any necessary actions;

d. Ensuring any health-care provider under investigation is afforded a fair hearing according to the prescribed procedures established by the CHMO (see Appendix E);

e. Convening a Medical Review Board, as required, to review all cases of adverse privileging actions for privileged health-care providers as established in Appendix E;

f. Determining if any reporting of an adverse credentialing action should be reported to appropriate authorities, including the National Practitioner Data Bank. Only the CHMO will make the report if it is deemed appropriate; and

g. Maintaining all records associated with any medical incident investigation.

2.2.2 Center Chief Medical Officers/Medical Directors, in collaboration with NASA Center Occupational Health Contracting Officer Technical Representatives (COTRs) or the official that serves as a COTR, when appropriate, and in the case of the Johnson Space Center, the Chief of Space Medicine and/or the Clinical Services Branch Chief, shall be responsible for:

a. Notifying the CHMO in writing (e.g., letter and/or e-mail) of any medical incidents occurring at their Center or facility that may warrant a formal medical incident investigation;

b. Overseeing/conducting a medical incident investigation, including assignment of impartial investigating officers where appropriate, according to the proscribed procedures established by the CHMO and noted in Appendix D;

c. Providing to the CHMO the results of a medical incident investigation and all relevant records and data collected during the investigation; and

d. Report to the CHMO any temporary or permanent limitation of privileges, as described in Appendix E, for a privileged health-care provider, pending investigation, and establishment of a Medical Review Board.

2.2.3 No individual shall conduct or oversee the investigation of a reported medical incident in which they were personally and directly involved. Where necessary, such investigation shall be conducted by another NASA facility with the approval of the CHMO.

Chapter 3. Confidentiality of Medical Quality Assurance Records

3.1 Introduction

3.1.1 NASA medical operations shall maintain a system of records for physician credentialing information and medical quality assurance activities. The records include, but are not limited to, records associated with activities conducted by civil servants, detailees to NASA, contractors, or consultants related to the provision of medical, dental, or psychological care, and any committees or other review bodies responsible for medical quality assurance.

3.1.2 The records associated with these activities shall include: patient care, assessment, and medical and behavioral health records; health-care provider credentialing and privileging records of health-care providers; and information collected and compiled for quality assurance reviews and assessments.

3.1.3 The records shall include the clinical and health-care provider instructions, clinical and medical procedure records, and records of all ancillary medical activities required to prescribe quality assurance activities, including closely related specifications such as required qualifications of personnel, procedures, and equipment.

a. The records shall include the instructions or procedures that establish a records retention program consistent with applicable regulations and NASA policy requirements and designate factors such as duration, location, and assigned responsibility.

3.1.4 Medical Quality Assurance (QA) records created by or for NASA, as part of a medical QA program, shall be confidential and privileged. They may not be made available to any person, except in those cases described in sections 3.2 and 3.3, under the "Freedom of Information Act" (Section 552) and the "Privacy Act" (Section 552a) of Title 5, United States Code.

3.1.5 As a system of records, QA records are within the purview of the "Privacy Act" of 1974, as amended and, therefore, the health-care provider who is the subject of a QA action may be entitled access to the records. With the exception of such a provider, the identities of third parties in the record (i.e., any person receiving health-care services from NASA or any other person associated with the NASA QA program) shall be redacted from the record before any disclosure of the record is made outside the Agency. No part of any medical QA record may be subject to disclosure, except pursuant to applicable law.

3.1.6 No part of any medical QA record shall be subject to discovery or admitted into evidence in any judicial or administrative proceeding, except in those cases described in sections 3.2 and 3.3, under the "Freedom of Information Act," or under applicable law.

3.1.7 A person who reviews or creates medical QA records for NASA or who participates in any proceeding that reviews or creates such records shall not testify in any judicial or administrative proceeding on such records or on any finding, recommendation, evaluation, opinion, or action taken by such person or body for such records, except in those cases described in sections 3.2 and 3.3, under the "Freedom of Information Act," or under applicable law.

3.1.8 A person or entity having possession of medical QA records, or access to medical QA records or testimony, shall not disclose the contents of such record or testimony in any manner or for any

purpose, except in those cases described in sections 3.2 and 3.3, under the "Freedom of Information Act," or under applicable law.

3.2 Access to Quality Assurance Records and Documents Within the Agency

3.2.1 Access to confidential and privileged quality assurance records and documents shall be restricted to NASA employees (including detailees, consultants, and contractors) who have a need for such information to perform their government duties or contractual responsibilities and who have been granted authorized access by the Chief Health and Medical Officer (CHMO).

3.2.2 To foster continuous quality improvement, NASA medical personnel may have access to confidential and privileged quality assurance records and documents relating to evaluation of the care they provide.

3.2.3 Any quality assurance record or document, or the information contained within them, whether confidential and privileged or not, shall be provided to the NASA Inspector General upon request. A written request is not required (a written record of the request will be maintained by the Office of the Chief Health and Medical Officer).

3.3 Non-NASA Disclosure of Quality Assurance Records and Documents

3.3.1 For any disclosure made for the purposes described in this section, and not necessary to achieve those purposes, the name of, and other identifying information regarding any individual patient, employee, or other individual associated with NASA shall be redacted from any confidential and privileged quality assurance record or document before any disclosure is made. NASA medical QA records may be authorized for disclosure or testimony to the following:

a. Any survey teams, national accreditation agencies or boards, and other organizations requested by NASA to assess the effectiveness of quality assurance program activities or to consult regarding these programs;

b. Any committees, panels, or boards convened by NASA to review Agency policy and practices. Any Federal executive agency or private organization, which will, if necessary, license, accredit, or monitor NASA health-care facilities;

c. Any proceeding commenced concerning the termination, suspension, or limitation of their clinical privileges for a present or former NASA civil servant or NASA assigned detailee, contractor, or consultant care provider;

d. A governmental board or agency or a professional health-care society or organization, if necessary, to perform licensing, or privileging, or to monitor professional standards for a health-care provider who is or was an employee of NASA, detailed to NASA, or a NASA contractor, or consultant assigned to NASA;

e. Other Federal agencies, upon their written request, to permit NASA's participation in health-care programs including health-care delivery, research, planning, and related activities with the requesting agencies. If NASA decides to participate in the health-care program with the requestor, the requesting agency must enter into an agreement with NASA to ensure that the Agency and its staff maintain the confidentiality of any quality assurance records or documents shared with the

Agency;

f. Civil or criminal law enforcement governmental agencies or instrumentalities charged under applicable law with the protection of public health or safety, including state licensing and disciplinary agencies, if a written request for such records or documents is submitted by an official of the organization, if the request states the purpose for which the records will be used, and if the purpose for the records is authorized by law;

g. Federal agencies charged with protecting the public health and welfare, Federal, state, and private agencies which engage in various monitoring and quality control activities, agencies responsible for licensure of health-care facilities or programs, and similar organizations, if a written request for such records or documents is received from an official of the organization and the request states the purpose for which the records will be used;

h. A hospital, medical center, or other institution that provides health-care services, if needed by such institution to assess the professional qualifications of any health-care provider who is, or was, an employee or contractor of NASA and who has applied for, or has been granted, authority or employment to provide health-care services in or on behalf of such institution; and

i. The General Accounting Office or committee of Congress if such records or documents pertain to any matter within their jurisdiction.

j. A court of competence jurisdiction, pursuant to a protective order.

3.4 Responsibilities

3.4.1 The CHMO shall be responsible for ensuring that each NASA clinic has developed policies and procedures for:

(a) Monitoring of QA recordkeeping processes and practices to assure appropriate implementation of this policy and issuing any additional requirements necessary for its implementation, and

(b) Maintaining a record of requests for access to NASA medical QA records as described in this policy.

3.4.2 Center Chief Medical Officers/Medical Directors, in collaboration with NASA Center Occupational Health Program Managers, and in the case of the Johnson Space Center, the Director of the Flight Medicine Clinic, shall be responsible for:

a. Maintaining medical QA records and assuring such records meet privacy requirements as described in this policy;

b. Reporting to the CHMO in writing (e.g., letter and/or e-mail) any requests for disclosure of medical QA records; and

c. Providing medical QA records only to approved recipients as described in this NPR.

Appendix A. Definitions

A.1 Clinical privileges -- Those specific medical, surgical, diagnostic, and therapeutic procedures that are within the scope of privileges granted to a member of the medical staff, defining the limits of patient care services a practitioner may render.

A.2 Competence -- Having the knowledge, skills, and abilities to provide a level of care that is acceptable to the medical community of peers.

A.3 Credentials -- Documented evidence of licensure, education, and training.

A.4 Health-care delivery -- The supervision, monitoring, or direct delivery of prevention, treatment, and management of illness and the preservation of mental and physical well-being through the supervision of, monitoring of, or the direct delivery of services offered by the medical, nursing, and allied health professionals.

A.5 Health-care provider -- The licensed independent practitioner responsible for overall medical or psychological care and treatment of each patient (e.g., medical, nursing, and allied health professionals who provide services without direction or supervision).

A.6 Health-care support personnel -- The licensed personnel (e.g., nurses, pharmacists, dietitians, certified athletic trainers, and other allied health professionals who provide services with direction or supervision) and non-licensed personnel (e.g., lab and x-ray technicians, emergency medical technicians (EMTs), dental assistants, strength and conditioning specialists, and wellness counselors who are under direction or supervision) who provide health-care support services in the NASA medical system.

A.7 Medical Incident -- A deviation from the standard of care occurring in the NASA health-care system, as perceived by the patient, another practitioner, or a reviewing quality monitoring body, including any medical incident in which undue harm, illness, morbidity, or mortality or excessive financial burden to the patient or agency occurs as a result of the care provided or omitted. This includes, but is not limited to, a missed diagnosis, incorrect diagnosis, therapeutic error, delay of diagnosis and/or treatment, admissions as a result of delayed diagnosis or treatment, complication of treatment, any incident with NASA medical system-wide implications, any incident in which legal recourse or claims for perceived malpractice or negligence has been brought by the patient or the patient's guardian, and any incident in which there has been a perceived moral or ethical breach of appropriate practitioner conduct.

A.8 Medical quality assurance program -- A comprehensive program within NASA to systematically review and improve the quality of medical and behavioral health services to ensure the safety and security of persons receiving medical and behavioral health services, and the efficiency and effectiveness of the utilization of staff and resources in the delivery of medical and behavioral health services. It includes any activity carried out by or for NASA to assess the quality of medical care.

A.9 Peer -- A professional colleague with similar training and clinical experience.

A.10 Peer review -- Peer review is the activity of looking objectively at the quality of care and practice of a provider. This is accomplished by peers looking at performance-based clinical practice, records, and other applicable data.

A.11 Primary source verification -- Obtaining and verifying credential information directly from the originating source such as a university, medical boards, and state and Federal licensure authorities.

A.12 Quality assurance records -- The proceedings, discussion, records, findings, recommendations, evaluations, opinions, minutes, reports, and other documents or actions that emanate from quality assurance committees, quality assurance programs, or quality assurance program activities.

A.13 Standard of Care -- The accepted or correct actions of a provider, taken in order to arrive at a diagnosis or to implement treatment for a given disease, disorder, or patient problem, adjusted for the patient's presentation and other conditioning factors. The standard of care is what is generally accepted in the health care discipline or specialty involved as reasonable and appropriate and is determined by peer review.

A.14 Statement of Exceptions and Corrections -- The response of a provider, who has requested a Fair Hearing, to the Hearing Committee Final Report.

A.15 Verification -- The confirmation of the appropriateness, currency, and authenticity of any licensure, certification, or training credentials of a health-care provider.

Appendix B. Acronyms

ACLS -- Advanced Cardiac Life Support

AED -- Automated External Defibrillator

BLS -- Basic Life Support

CHMO -- Chief Health and Medical Officer

CMO -- Chief Medical Officer

COTR - Contracting Officer Technical Representative

CPR -- Cardiopulmonary Resuscitation

EMT -- Emergency Medical Technician

MD -- Medical Director

MRB -- Medical Review Board

MRO -- Medical Review Officer

OCHMO -- Office of the Chief Health and Medical Officer

OH -- Occupational Health

QA -- Quality Assurance

Appendix C. References

C.1 5 U.S.C. 552a, the Privacy Act of 1974, as amended.

C.2 NPR 1382.1, NASA Privacy Procedural Requirements.

C.3 NPD 1800.2, NASA Occupational Health Program (Revalidated 3/29/04).

C.4 NPD 1440.6, NASA Records Management.

C.5 NPR 1800.1 NASA Occupational Health Program Procedures, Chapter 2.2.

C.6 NPR 8715.2, NASA Emergency Preparedness Procedural Requirements.

C.7 NASA Occupational Health Medical Quality Assurance Program Employee and Management Directed Principles, Section II, Staff Qualifications and Competency.

C.8 Health Care Quality Improvement Act, as amended.

C.9 42 U.S.C. §§ 11101 & 11111 et.seq. , Health Care Fraud and Abuse Data Collection Program.

C.10 42 U.S.C. § 1320a-7e; 45 C.F.R. Part 60, National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners.

C.11 45 C.F.R. Part 61, Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners.

C. 12 14 CFR Part 1206 Availability Of Agency Records To Members Of The Public.

C. 13 14 CFR Part 1212 Privacy Act--NASA Regulations.

C. 14 14 CFR Part 1263 Demand For Information Or Testimony Served On Agency Employees; Procedures.

Appendix D. Medical Incident Investigation

D.1 Introduction

D.1.1 Medical incident investigations will be conducted by an independent panel according to the procedures noted below. The panel will include personnel with similar experience and expertise as those involved in the medical incident. Physician members shall be board certified and experienced in the appropriate area of interest.

D.2 Responsibilities

D.2.1 The Center Chief Medical Officer/Medical Director (CMO/MD) will ensure that the Chief Health and Medical Officer (CHMO) is notified of all medical incidents involving serious physical or psychological injury or death.

D.2.2 The Center Chief Medical Officer/Medical Director and Center Occupational Health Contracting Officer Technical Representative (COTR), or the appropriate official that serves as that COTR, will appoint the independent panel to investigate the incident.

D.2.3 The CHMO will appoint the investigating panel in cases involving the CMO/MD.

D.3 Process Description

D.3.1 Minimum factors the independent panel will consider include:

a. Human Factors such as:

- Proper training, certifications, and privileges;
- Competency;
- Fatigue (work-rest cycles);
- Judgment;
- Stressors (external and work related);
- Interpersonal relationships with coworkers; and
- Possible drug or alcohol influence.

b. Operational and System Factors such as:

- Communication issues;
- Biomedical equipment or technical failures;
- Staffing and scheduling issues;
- Proper procedure guidelines documented and implemented; and
- Proper supervision of clinical activities.

c. Witnesses - All witnesses will be informed that their statements may not be confidential and that they will be interviewed upon their consent.

d. Possible Criminal Behavior - If a criminal violation is suspected, the CHMO must be immediately notified in writing who, in turn, will notify appropriate NASA legal counsel (i.e., the Office of General Counsel and the Office of Inspector General). The investigation will stop pending further guidance from the CHMO and the appropriate NASA legal counsel.

D.3.2 The panel will determine if the standard of care was met.

D.3.3 The panel will report findings and provide all relevant records and data collected to the CHMO. The CHMO may convene the Center CMOs and/or elements of the Medical Policy Board to review the investigation results and recommend actions. Adverse actions taken against privileged providers will be performed in accordance with Appendix E.

Appendix E. Adverse Actions and Fair Hearing Procedures

E.1 Adverse Privileging Actions

E.2 Introduction

E.2.1 When a privileged medical provider's mental or physical condition, conduct, or clinical performance requires action to temporarily limit their clinical privileges, the Center Chief Medical Officer/Medical Director may do so, with the concurrence of the Chief Health and Medical Officer (CHMO), pending additional information or investigation.

E.3 Responsibilities

E.3.1 The CHMO will assign an independent investigating officer and a Medical Review Board (MRB) of peers to investigate and make recommendations regarding provider privileges.

E.3.2 The investigating officer will perform a thorough and impartial investigation of all issues related to the temporary abeyance or suspension of privileges.

E.3.3 The MRB of provider peers will review the investigating officer's findings and makes impartial recommendations to the CHMO regarding privileges.

E.4 Process Description

E.4.1 Temporary limitations placed on a provider's clinical privileges are in the form of an abeyance or suspension of those privileges.

a. Abeyance - An abeyance is a temporary limitation of some, or all, clinical privileges. This is not considered an adverse privileging action unless the investigation results in subsequent adverse actions. If no adverse action is indicated, the provider is reinstated and no entry is made in the providers credentials/privileges file and no reports are made to regulatory agencies. The provider must be notified, in writing, that clinical privileges are being placed in abeyance pending additional information or investigation.

b. Suspension - In cases where there is reasonable belief that the action is warranted by the facts, provider misconduct, professional incompetence, or negligence that poses a threat to the safety of patients, a suspension of clinical privileges may be used. A suspension is an adverse privileging action which must be disclosed by the provider for future licensing, privileging, and insurance purposes, even if the outcome is full reinstatement of privileges. Appropriate reports are made to regulatory agencies.

The provider must be notified in writing of the suspension of privileges pending an investigation, the reason for the investigation, and the length of the suspension. Resignation from employment of a provider following suspension of privileges shall not prevent the investigation and final recommendations process from continuing.

c. For all temporary adverse privileging actions, the CHMO will assign an independent investigating

officer and an MRB consisting of professional peers that are impartial to the case. The MRB will review investigation findings and make final recommendations to the CHMO for evaluation and implementation. The provider does not have the right to present his/her case to the MRB but may provide a written statement for consideration.

E.4.2 The MRB will make one of the following recommendations:

a. Reinstatement of Privileges - There are no recommendations to limit or revoke clinical privileges. There may be recommendations for additional monitoring and evaluation. This is not an adverse privileging action following abeyance of privileges;

b. Restriction of Privileges - Restriction is a temporary limit placed on all or a portion of a provider's clinical privileges. This may require some direct supervision for some clinical duties. Privileges may be reinstated at a later date;

c. Reduction of Privileges - Reduction is a permanent removal of a portion of a provider's privileges;

d. Revocation of Privileges - Revocation is the permanent removal of all clinical privileges; and

e. Denial of Clinical Privileges - Denial of privileges occurs when an application for privileges or renewal of privileges is denied for substandard performance, professional misconduct, or impairment.

E.4.3 All documents related to adverse privileging actions, including all of the processes noted above, will include the following statement on the bottom of each document: "Medical Quality Assurance (QA) records created by or for NASA, as part of a medical QA program, are confidential and privileged." No part of any medical QA record may be subject to disclosure, except pursuant to applicable law.

E.5 Fair Hearing Process

E.5.1 Introduction

E.5.1.1 Any provider whose clinical privileges are denied, restricted, reduced, or revoked may request a Fair Hearing within 30 business days of notification of the adverse action. Adverse action notification will consist of the action taken and any supporting information or records.

E.5.2 Responsibilities

a. The CHMO will appoint a Hearing Committee when requested by a provider who has had an adverse privileging action. The CHMO reviews all documentation and provides final notification of findings and recommendations to the provider as required.

b. A legal representative will be appointed to oversee the Fair Hearing process as noted below.

c. The Hearing Committee Chairperson and members will conduct a fair and impartial hearing and make final recommendations to the CHMO based on the preponderance of evidence.

E.5.3 Process Description

E.5.3.1 Upon receipt of a request for a Fair Hearing, the CHMO will appoint a Hearing Committee of three providers with one assigned as Chairperson and at least one member a peer to the provider, based on clinical experience and training.

E.5.3.2 The CHMO will notify the provider in writing of:

a. The date, time, and location of the hearing;

b. The provider's right to be present, present evidence, and call witnesses;

c. The names of witnesses to be called by NASA;

d. The right to cross-examine all witnesses; and

e. The right to have legal counsel present.

E.5.3.3 The Hearing Committee may question all witnesses and examine all documents, as necessary. The Chairperson will arrange for orderly presentation of evidence and witnesses. The investigating officer may testify before the Hearing Committee. A verbatim record of the proceedings is required. This may require contracting the services of a court reporter who will provide a written transcript in a timely manner.

E.5.3.4 After hearing all testimony and considering all evidence, the Hearing Committee will make a written recommendation to the CHMO. Findings and recommendations will be completed as soon as possible and signed by all committee members. A "preponderance of evidence" and "standard of care" standards will be applied, meaning the greater weight of credible evidence without the requirement for proof beyond a reasonable doubt. Final recommendations may include a minority report, if the committee is not in unanimous agreement. The final report and transcript will be provided to the CHMO and the provider involved within 30 business days of the hearing completion.

E.5.3.5 The provider has ten business days to review the final report and transcript and provide a Statement of Exceptions and Corrections.

E.5.3.6 The CHMO will review the Hearing Committee Final Report, the hearing transcript, and the provider's Statement of Exceptions and Corrections prior to making written notification of the final decisions and adverse actions, if any. The provider must be notified of the right to appeal the findings within ten business days of receipt of the final letter.

E.5.3.7 The appeal process will include review of all documents by a NASA legal advisor and a medical provider consultant with appropriate specialty training, neither of whom being involved in the process thus far. These advisors will make recommendations to the CHMO who will then issue a final recommendation.

E.5.3.8 After final disposition is made, the appropriate regulatory agencies (e.g., National Practitioner's Data Base) will be notified regarding the adverse privileging action.

E.5.3.9 All documents related to the Fair Hearing process, including all of the processes noted above, will include the following statement on the bottom of each document: "Medical Quality Assurance (QA) records created by or for NASA, as part of a medical QA program, are confidential and privileged." No part of any medical QA record may be subject to disclosure, except pursuant to applicable law.