Presentation to the Institute of Medicine

Ethics Principles and Guidelines for Health Standards for Long Duration and Exploration Spaceflights

Astronaut Office

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Astronaut Office actively supports readdressing the policies for crew health standards for exploration class missions beyond low Earth orbit (LEO)

– NASA will likely exceed current medical standards to effectively pursue Exploration beyond LEO; therefore, lifetime consequences to the individual should be minimized through active monitoring and treatment.

– An appropriate risk strategy should seek a balance between the mission technical risk, the mission crew medical risk, and the lifetime crew medical risk.

– These charts will focus on health risks to the astronauts, and not the details of technical or scientific relative merits of one exploration mission over another.
Topics for Discussion

• Risk Assessment from Astronaut Perspective
  – Technical Mission Risk
  – Crew Medical Mission Risk
  – Lifetime Crew Medical Risk
• Occupational Surveillance
• Implications for Exploration
• Panel Questions to the Astronaut Office
Aggregate risk of loss of crew/vehicle allows comparison across missions/platforms.

Apollo lunar mission aggregate risk was ~1/11 (actuarial approach*)
  - If Apollo 13 had resulted in loss of crew/vehicle, risk would have increased to ~1/6
  - While all Apollo missions were successful, such a small data set results in large uncertainties
  - No medical mission or lifetime crew risk was included in these assessments

Shuttle mission aggregate risk
  - Was ~1/46 (actuarial approach)
  - No medical mission or lifetime crew risk was included in these assessments

*The actuarial approach is a fairly simplistic mathematical Bayesian process for assessing demonstrated reliability, which is based on the number of successes/failures from previous “attempts,” and where continued successful “attempts” result in both increased mean demonstrated reliability and reduced uncertainty bands.
Currently risk assessments are routinely performed at NASA to make relative risk decisions.

- Probabilistic risk assessments (PRA) and others (see example PRA in backup)
- Estimates only, differences of 10, 100, 1000-fold are meaningful scales

Historical examples illustrate how actual risk evolved with further understanding, vehicle modifications, etc.

- Shuttle retrospective PRA for first flight was approximately 1/10 vs. 1/90 for the 135th flight

Multi-Purpose Crewed Vehicle Program Probabilistic Risk Assessment Requirements Document 70017, section 6.2 acknowledges that the “risk of the first flight may be greater than an order of magnitude” of the predicted risk based on “unknown” risks.
Current Mission Risk Assessments

- ISS Missions routinely evaluated
- 6 month mission risk-PRA
  - Primary contributors are medical issues and MMOD
    - LOC (1 or more) due to medical issue ~1/230
    - LOC (all) due to MMOD ~1/350
  - LOCV ~1/2700
  - LOC due to vehicle collision ~1/6200
  - LOC due to fire ~1/320,000
  - Aggregate LOC, on-orbit portion is ~1/130

- Soyuz (actuarial approach)
  - LOCV ~1/190

- Aggregate 6 month on ISS + Soyuz ~1/67
- Aggregate 12 month on ISS + Soyuz ~1/47
- Lifetime crew medical risk is assessed separately
  - Increased cancer mortality limited to <3%
Mission & Long Term Medical Risk History

Known risks during Shuttle and ISS mission design:

• Initial predicted decompression sickness was an EVA risk expected to impact >20% of crew
• No cases have been reported in >300 EVA person sorties using the US EVA suit

Unknown risks during Shuttle and ISS mission design:

• Uncertainties with respect to long term bone strength
• Microgravity ocular syndrome was unknown until recently
• Others may only be detected with long term occupational health and surveillance program
## ISS Mission Risk Relative to Other Activities

Comparison to one 6-month LEO spaceflight*:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coal Mining</td>
<td>62 yr</td>
</tr>
<tr>
<td>Farming-crop</td>
<td>48 yr</td>
</tr>
<tr>
<td>Construction Laborer</td>
<td>44 yr</td>
</tr>
<tr>
<td>Timber Cutting</td>
<td>14 yr</td>
</tr>
<tr>
<td>Crop Duster</td>
<td>9 yr</td>
</tr>
<tr>
<td>Alaskan Shell Fisherman</td>
<td>5 yr</td>
</tr>
<tr>
<td>Firefighter on Sept 11, 2001</td>
<td>1 event</td>
</tr>
<tr>
<td>Motorcyclist Attempt Mt. Everest Climb</td>
<td>26 yr</td>
</tr>
<tr>
<td>Tour in Iraq on the Ground</td>
<td>3 yr</td>
</tr>
<tr>
<td>D-Day US Infantryman</td>
<td>1 event</td>
</tr>
</tbody>
</table>

*No long term medical considerations included*
Future Mission Risk Assessments

14-day Lunar Orbit planning target ~1/130 (based on PRA)
  – Expect first missions to be 10-fold riskier based on “unknown” risks at the beginning of new programs

Risk Assessments will be required for each exploration class mission
  – Asteroid Mission (~90d+)
  – Lunar Surface Mission (~1 week – 6 months)
  – Mars Surface Mission (520d, 840d, 940d)
Medical Mission Risk

ISS LOC numbers illustrate that in-flight medical issues are a significant portion of the risk analysis (Integrated Medical Model predictions)

– LOC (one or more) as result of medical issue ~1/230
– Well-balanced when compared to overall 6 months + Soyuz risk of ~1/67 (about 1/3 of total PRA predicted risk)
– Drivers: acute onset vascular disease, surgical abdomen, etc

Medical mission is risk expected to increase for Exploration missions due to:

– Limited onsite medical capability
– Lack of immediate medical return
– Work and environment (surface operations, radiation)
– Duration

Safe Passage, 2001, p. 29 "Travel into deep space beyond Earth orbit involves many unique and hazardous elements:

– Isolation. Great distances preclude timely evacuation and a return to Earth for health care. Therefore, the crew must be prepared to deal in flight with diverse medical situations ranging from minor cuts to death. ... 
– Space-specific hazards. The space environment lacks gravity and contains damaging radiation.“
Medical standards have been developed for those areas associated with long term health
- Radiation exposure
- Changes in bone
- Occupational exposure to toxic substances

Other lifetime medical risk assessments have yet to be developed
- Microgravity ocular syndrome
- Musculoskeletal injury (space suit training injury)
- Immune function alterations

Lifetime medical risk is not managed in same fashion as technical and mission risk
- Strategy has been to use criteria from other professions or judgment to drive lifetime medical risk into background levels
- Comprehensive strategy for monitoring and addressing issues is not in place and is needed
Safe Passage, 2001, p.7, Recommendation 2: “NASA should develop a comprehensive health care system for astronauts…”

The Lifetime Surveillance of Astronaut Health (LSAH) does a good job at archiving and analyzing health data across mission phases
- LSAH is NOT a lifetime Occupational Health Program
- Deliberate program for monitoring for outcomes of occupational risks is not performed/funded as part of LSAH

NASA is not currently authorized to build a program of deliberate monitoring, diagnosis and treatment of medical issues related to occupational exposures (similar to Dept of Energy, Dept of Defense, see backup slide)
- As of Jul 2013, no health care system is available to provide long-term occupational surveillance for astronauts.
- Amendment to the 2014 NASA Authorization Act, if approved, will authorize this and is now under discussion in Congress.

Complete understanding of the comprehensive human response to spaceflight is not possible without such a program
Astronaut Mortality

<table>
<thead>
<tr>
<th>Lifetime Surveillance of Astronaut Health (n=330 US Astronauts)</th>
<th>Total</th>
<th>Living</th>
<th>Deceased</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Shuttle</td>
<td>38</td>
<td>25</td>
<td>13</td>
</tr>
<tr>
<td>Shuttle (Any US Astronaut that flew a Shuttle mission, but did not fly long duration missions)</td>
<td>218</td>
<td>194</td>
<td>24</td>
</tr>
<tr>
<td>Long Duration Experienced (Includes any US Astronauts who has flown a long duration mission, including MIR)</td>
<td>46</td>
<td>46</td>
<td>0</td>
</tr>
<tr>
<td>Never Flew (any US Astronaut selected who has never flown a mission either because they left the corps before their mission or have not had the opportunity to fly yet)</td>
<td>28</td>
<td>17</td>
<td>11</td>
</tr>
</tbody>
</table>
Implications for Exploration

**Astronauts don’t do risky things because they are risky**

- We expect the technical/scientific value of the mission will be assessed and compared to the technical/crew medical mission risk and lifetime crew medical risk for each particular exploration mission.
- Each individual astronaut will also make their own decision of merit after the Nation/Agency completes the assessment above.

**Current discussion on ethics of health risks for exploration applies to a very small number of individuals**

- Infrequent missions and very small crews (4-6).

**Some aspects of mission, environment, and health impacts will be unknown, and therefore the limitations on exposures will require continual re-evaluation**

- Requires systematic study and collection of long term occupational health data in order to validate (or not) our understanding.
- Safe Passage, 2001, p.7, Recommendation 2: “NASA should develop a comprehensive health care system for astronauts...”
Radiation Exposure

In Dec of 2000, the National Council on Radiation Protection and Measurement (NCRP) released a report entitled "Radiation Protection Guidance for Activities in Low-Earth Orbit," NCRP Report No. 132. This report continues the stance of limiting occupational radiation exposures of individuals to that associated with a 3% excess relative risk of cancer mortality.

- ~1% is used as an Administrative limit to ensure 3% excess with 95% Confidence Interval (due to wide uncertainty band)

When challenged to identify a crew for an upcoming 12 month mission to the ISS, the number of available candidates was extremely low (effectively 3 candidates for 2 positions)

- Repeated 12 month missions to the ISS are not sustainable with all current programmatic and health constraints.

For exploration missions, if the radiation exposure limit is reassessed:

- A strategy of occupational surveillance to monitor for the predicted increase in cancer formation, heart disease, and brain function would be appropriate, and could be applied to future modeling efforts.

- A surveillance effort for early detection of cancer formation may reduce risk of mortality.

Since there is not a specific space radiation cancer, attribution to spaceflight will need to be accomplished statistically.

- May take a generation or more to assess, assuming occupational surveillance is performed.
Panel Questions to Astronaut Office

• Are risk considerations different for long duration and exploration missions? Does the risk management approach change?

  – Yes. *Relative mission risk for future exploration missions is expected to be greater than missions to LEO, so considerations are expected to be different.*
  – *There are also anticipated increases in medical risks during exploration missions and there are no easy return options (no lifeboats...).*
  – *Lifetime crew medical risks may also be greater, but should be balanced with the mission risks*
  – *Crew medical risk will vary dramatically with the type of exploration mission designed/planned, so a flexible approach to handling mission crew medical and lifetime crew medical risks should be developed (i.e. one that can be adapted to maintain a risk balance as missions change).*

  – *Safe Passage, 2001, p. 4 – p. 4* "The unique environment of deep space presents challenges that are both qualitatively and quantitatively different from those encountered in Earth orbit. Risks are compounded by the impossibility of a timely return to Earth and of easy resupply and by the greatly altered communications with Earth."
In light of the unknowns and uncertainties how much risk can be taken?

– *We, as an Agency, should always strive to minimize risks in our vehicles, in our astronauts, and in astronaut lifetime survivability*

– *We should balance the mission technical risk and crew medical risk with the crew lifetime medical risks.*

– *Overly conservative lifetime medical standards could limit worthwhile exploration, particularly for cases where the mission technical risk is also likely to be very high.*
Who makes those decisions (concerning exploration risk)?

– At the national (and International) level Agency goals for exploration are defined.
– The Agency develops mission plans and makes recommendations to the political level for decision.
  • Astronaut Office participates with the Programs and Control Boards during development and refinement of these mission plans.
  • Technical authorities and Astronaut Office (via JSC Center Director) input is provided for human ratings endorsements for the mission plans.
– After the Agency (with endorsement at the political level) has defined the risk, each crewmember must also decide if the job/mission risks are acceptable for them.
What data and considerations go into those decisions?

– Astronaut Office provides operational and test expertise during the development of exploration plans and programs. The office is eligible to contribute at all levels in support of technical development and assessment boards.

– From an individual perspective, crew members evaluate the risk data that is made available by the programs and make their own judgment relative to risk and mission value.
Panel Questions to Astronaut Office

What input do astronauts have into decisions regarding risk and health standards? What are the processes for that input?

- Limited participation in lower level boards with astronaut office representatives as ad hoc / ex officio members (Human System Risk Board, Commercial Spaceflight and Exploration requirements development, etc.)
- Minimal input into upper level boards (Medical Policy Board)
- Review of medical standards documents
- Participation in the standards development for each design reference mission
- Recommend Astronaut Office representation at forums where decisions are made for specific standards and policies for health risks and compared to individual mission merits
Astronaut Office actively supports readdressing the policies for crew health standards for exploration class missions beyond low Earth orbit (LEO)
  – NASA will likely exceed current medical standards to effectively pursue Exploration beyond LEO; therefore, lifetime consequences to the individual should be minimized through active monitoring and treatment.

An appropriate risk strategy should seek a balance between the mission technical risk, the mission crew medical risk, and the lifetime crew medical risk
  – Astronaut Office representation in this decision and policy process would be appropriate

Occupational surveillance is critical to complete understanding of human space flight

In the future, crew medical and lifetime crew health considerations will have to be balanced relative to the merits of the exploration mission
The breakdown is an example of the most significant factors in the shuttle PRA

- **LOCV** = Loss of Crew and Vehicle is a meaningful tool for mission/vehicle comparison
• **DoE’s** Former Worker Medical Screening Program provides ongoing medical screening examinations at no cost to all former DOE federal, contractor, and subcontractor workers who may be at risk for occupational diseases.

• Radiation doses monitored during work careers

• Medical surveillance following retirement for health effects that may be causally related to their occupational radiation exposure
  – Following a deliberate screening template, surveillance tests for specific cancers at specific intervals
Appendix F Human-Rating Certification

Program Name:

Scope of Certification (Systems and Reference Missions Covered in this Human-Rating Certification):

Check here if Additional Scope Information is attached

Duration of Certification:

In accordance with NPR 8705.2b, the Program identified above has satisfactorily completed the Human-Rating Certification activities and has satisfied the technical requirements for human-rated systems, except as noted within the approved waivers and exceptions contained within the Human-Rating Certification Package. I request that the Program identified above be granted Human-Rating Certification within the scope described.

Program Manager

PROGRAM CONCURRENCE

I endorse and concur with the request to grant the Human-Rating Certification within the scope described.

Associate Administrator, Exploration Systems Mission Directorate

Associate Administrator, Space Operations Mission Directorate

TECHNICAL AND RISK CONCURRENCE

Within the scope of my authority I endorse and concur with this request to grant the Human-Rating Certification within the scope described.

Chief, Safety and Mission Assurance (Technical Authority)

Chief Engineer (Technical Authority)

Chief Health and Medical Officer (Technical Authority)

Director, Johnson Space Center (Consent for Crew Risk)

CERTIFICATION

I certify the Program to be human-rated within the scope described.

Associate Administrator

The Various Program TAs sign endorsement page

JSC Center Director serves as the voice of the crew
# Appendix E: Human-Rating Certification Package Endorsements

## HUMAN-RATING CERTIFICATION PACKAGE ENDORSEMENTS

**Name of Program:**

**Scope of Certification (Systems and Reference Missions Addressed in the Human-Rating Certification Package):**

- [ ] Attach

**The Human-Rating Certification Package for SR, SDR, PDR, LDR, MDR is complete and is provided for your approval.**

**Program Manager:** ____________________________  **Date:** ______________

Within the scope of my Authority, I endorse and approve this Human-Rating Certification Package and indicate:

1. For the identified Milestone, and pending satisfactory completion of open items identified at the SR, SDR, PDR, LDR, MDR, the Human-Rating Certification Package is satisfactory and represents acceptable progress toward formal Human-Rating Certification in conjunction with flight readiness determination.
2. All Human-Rating Certification Package-related items identified at the previous Milestone have been satisfactorily resolved and documented.
3. All waivers and exceptions to human-rating certification requirements or technical requirements for human-rated systems have been reviewed and satisfactorily disposed.

### Required Signatures

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<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>Chief, Safety and Mission Assurance (Technical Authority)</td>
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<tr>
<td>Chief (Engineer) (Technical Authority)</td>
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<tr>
<td>Chief, Health and Medical Officer (Technical Authority)</td>
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<tr>
<td>Director, Johnson Space Center (Consort for Crew Risk)</td>
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**Reservations (Y/N):**