Acceptable Risk

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What is acceptable?

The major goal of NASA's space radiation research is "to enable the human exploration of space within acceptable risks from space radiation." Inevitably, the first question that arises is about the meaning of "acceptable". In context, it is an *a priori* determination, not an a *posteriori* statement of the level of risk that has been accepted. It is an assessment of the probability distribution that a given set of consequences will be caused by exposure to space radiation, and acceptability is given by the extent to which missions will be constrained in order to maintain the risk within given probability boundaries.

An excellent discussion of this topic can be found in an article by Krewski.[1] He asserts that "acceptable risk" is "the likelihood of an event whose probability of occurrence is small, whose consequences are so slight, or whose benefits (perceived or real) are so great, that individuals or groups in society are willing to take or be subjected to the risk that the event might occur." This concept evolved from the realization that human activity cannot be conducted with absolute safety, and that risks commonly, and implicitly, found to have been accepted by common practice, could be used to provide explicit safety guidelines.

Krewski presents two ways of establishing acceptable risk. One of these, the "revealed preference" approach, is the method used by the National Council on Radiation Protection and Measurements (NCRP)[2] to make the recommendations used by NASA. It is known as a "revealed preference" approach, based on a review of life shortening attributed to occupations in which humans engage regularly, and which appear to be condoned by society. The other method is based on public consultation and the NCRP has occasionally had recourse to this method as well.[3]

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[1] Krewski, Daniel. 2002. "Acceptable Risk." Encyclopedia of Public Health. Ed. Lester Breslow. Gale Cengage,. eNotes.com. http://www.enotes.com/public-health-encyclopedia/acceptable-risk

[2] National Council on Radiation Protection and Measurements. 2000. Radiation Protection Guidance for Activities in Low-Earth Orbit. NCRP Report No. 132 http://www.ncrponline.org/

[3] National Council on Radiation Protection and Measurements. 1997. Acceptability of Risk From Radiation – Application to Human Space Flight. Symposium Proceedings No. 3. Workshop held May 29, 1996 in Arlington, VA.

Acceptable to whom?

The next question that needs to be asked is the corollary, “Acceptable to whom?” The answer to that question depends on who is asked. While a potential astronaut might be willing to go an a one-way trip to any extraterrestrial destination, his or her spouse and children might have a different perspective; so might the astronaut’s mother and, almost certainly, the astronaut’s lawyer. Such an offer might stem from sincere abnegation, but could not be accepted except in the direst astrophysical circumstances, such as an impending asteroid impact. Otherwise, it would have to be rejected by a humane society that does not, as a matter of principle, engage in suicide missions to further its policies.

The purpose of space exploration is the pursuit of knowledge and the development of space as an economic, political and military resource. The whole point of sending human beings on the exploration of space is for them to come home safely, delivering information and treasure. There is no place in such a program for individuals looking upon space as an opportunity for adventure and personal aggrandizement. It would be impossible to explain to the taxpayer that NASA is paying to satisfy the megalomaniacal urges of that popular figment of the media imagination: a space cowboy.

Astronauts are not only employees, but also volunteers. They are not conscripted to serve on space exploration, but are participants in what will remain research as long as there are no permanent colonies in space. As a consequence, astronauts must be accurately informed of the risks they incur, and the benefits they, or society, expects to realize from their willingness to take such risks upon themselves. Furthermore, even if the level of risk they are required to incur is within the range of acceptability, it is understood that their employer – e.g., NASA – is required to make every reasonable effort to reduce the level of risk below any level deemed acceptable.

Informed Consent

The paradigm that applies to the risks that research subjects can be expected to assume is the notion of Informed Consent, that has been made a part of the laws of the United States.[4] This paradigm takes into account the interests of the participants, even if they do not wish to or are unable to enforce those interests. Requirements for meeting this goal include:

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[4] Code of Federal Regulations, TITLE 45□PUBLIC WELFARE. DEPARTMENT OF HEALTH AND HUMAN SERVICES. PART 46□PROTECTION OF HUMAN SUBJECTS. §46.116 General requirements for informed consent. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

- risks have been minimized so that they are comparable to the risks incurred by workers in a range of commonly accepted occupations.
- risk assessments are sufficiently accurate that the upper bound of risk estimates falls below the level considered acceptable.
- risks or discomforts (or to the embryo or fetus, if the crew member is or may become pregnant) have been adequately explained to every crew member.
- best practices and good faith efforts are made to ensure that risks are minimized below the acceptable level, including operational procedures that provide warning levels adequate to allow evasive actions.

These requirements, especially the last one, are consistent with the so-called ALARA (As Low As Reasonably Achievable) principle in radiation protection. They establish an ethical basis on which space exploration risks in general, as well as space radiation risks in particular, may be incurred.

NASA Implementations

The law leaves adequate leeway for Federal departments or agencies to develop appropriate processes for implementing its intent, which is the protection of human subjects. Taking applicable laws into consideration, radiation limits have been established, based on the following assumptions:[5]

- The exposed population is limited in size and limits apply only to flight crews during actual performance of a mission;
- NASA conducts a formal appraisal of radiation hazards before each mission including detailed calculations of mission risk;
- NASA maintains detailed radiation exposure records for each crew member, based on in-flight dosimetry;
- Mission design, flight planning and mission operations are conducted according to the ALARA principle;
- Formal operational procedures and rules covering any radiation exposure contingency have been developed and documented.

Human system standards have been developed by NASA following these principles, and are intended to ensure an appropriate environment for human habitation, qualified human participants, a necessary level of medical care, and risk mitigation strategies against the deleterious effects of space flight. The standards include exposure limits, fitness for duty criteria, permissible outcome limits, and nominal and off-nominal operating bands (intervals of relevant operational parameters within which it is appropriate or not to conduct a mission). The goals of these standards are to ensure mission completion, limit morbidity, and reduce the risk of mortality during Exploration-class missions. These standards are established and maintained under the direction of NASA's Chief Health and Medical Officer.

REID and PEL

There is significant uncertainty in prediction of the risks associated with a given quantity of radiation on biological tissue.[6] Risk of exposure-induced death (REID) is the currently preferred measure of risk, replacing the mathematically ill-defined excess relative risk with a probability density function. REID is the risk of an exposed individual dying from a certain cancer as a function of the effective dose. Permissible exposure limits (PELs) follow recommendations of NCRP Report 132[7] with modifications, including new epidemiology and uncertainty assessments, estimates of non-cancer risk, and acute effects. There are a number of different PELs—a thirty-day limit, a one-year limit, a career limit, etc. Career limits are based on a REID of 3 percent.

ALARA

Implementation of ALARA is not based on an arbitrary determination of what might be "reasonably achievable" but, instead, the operating limits for mission design and flight operations are set to correspond to the lower 95 percent confidence level of the risk probability. This ensures that mission designers and managers have recourse to a number of actions well before the PEL is reached. These actions may include the use of different materials and different interior material distributions on spacecraft, scheduling extravehicular activities (EVAs) for periods of reduced solar activity and no transit through radiation belts, use of radiation measurements to verify radiation exposure and provide warning for retreat to storm shelters.[8] Once the mission has been designed, it will include an estimated exposure. Crew members are selected so that the sum of their

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[6]Sinclair, Warren K. History of the development of radiation protection standards for space activities. National Council on Radiation Protection and Measurements. 1997. Acceptability of Risk From Radiation, pp. 51-65, op. cit.

[6] F. A. Cucinotta, W. Schimmerling, J. W. Wilson, L. E. Peterson, G. Badhwar, P. Saganti, and J. Dicello. "Space Radiation Cancer Risks and Uncertainties for Mars Missions." Radiat. Res. 156: (2001)156, 682–688.
[7] op.cit.

[8] Committee on the Evaluation of Radiation Shielding for Space Exploration, National Research Council. 2008. Managing Space Radiation Risk in the New Era of Space Exploration, 132 pages.http://books.nap.edu/catalog.php?record_id=12045

previous radiation exposure and their predicted radiation exposure is below the PELs. Following a successful mission, medical surveillance and control of further radiation exposures are required.