Federal Aviation Administration

Guidance on Informing Crew and Space Flight Participants of Risk

Version 1.1

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Federal Aviation Administration
Office of Commercial Space Transportation
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1.0	Baseline version of document	November 3, 2016
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A. INTRODUCTION

1. Purpose

Guidance on Informing Crew and Space Flight Participants of Risk details the Office of Commercial Space Transportation's (AST) policy and guidance on informed consent for crew and space flight participants. This document informs holders of a license or permit under 51 U.S.C. Subtitle V, chapter 509 ("operators"), as well as applicants and prospective applicants for such licenses and permits, on an acceptable means of complying with the commercial space informed consent laws, including the Commercial Space Launch Amendments Act of 2004, and its implementing regulations, namely, 14 CFR § 460.9 and § 460.45. It also compiles relevant legal interpretations and preamble to reduce the research burden associated with compliance.

2. Background

Section 50905 of Title 51 of the United States Code and part 460 of Title 14 of the Code of Federal Regulations require an informed consent regime for commercial human space flight. Section 460.9 requires an operator to notify in writing any individual serving as crew ~~that~~ if the United States Government has not certified any launch or reentry vehicle as safe for carrying flight crew or space flight participants ("non-certification statement"). Section 460.45 requires an operator to provide space flight participants with the same non-certification statement given to crewmembers as well as notify space flight participants of the hazards and risks of the launch or reentry in which they wish to participate.

All italicized information in this document is a direct quote from the Commercial Space Launch Amendments Act of 2004 (Statute), regulations, or preamble to the part 460 final rule. Additionally, this guidance incorporates the definitions found in 14 CFR § 401.5 and § 401.7.

Commented [A1]: Since publication of Part 460, the government (NASA) has implemented human spaceflight certification of certain orbital commercial vehicles. NASA HSF certification exceeds FAA Part 460 requirements and is currently considered a means of compliance. In future rulemaking, FAA should establish a similar qualification for human occupancy based on compliance with Part 460. This would be significantly different from the FAA aircraft certification approach, which is a result of a mature vs. nascent industry. Such differences are appropriate and necessary for the foreseeable future, until the number of space vehicles and flight frequency/history are sufficient to demonstrate reliability and risk consistent with aircraft certification standards. Clarification on the intent/meaning of human qualification (or certification as used in this guidance document and Part 460.9) such as fitness to carry occupants per Part 460 requirements (vs. meeting reliability and occupant risk requirements) would be useful in setting expectations for future rulemaking.

3. Applicability

> § 460.9 An operator must. . .
> § 460.45 . . . an operator must satisfy the requirements of this section

The informed consent requirements in § 460.9 and § 460.45 apply only to operators who have a human on board a vehicle. An operator is defined by § 401.5 as "a holder of a license or permit under 51 U.S.C. Subtitle V, chapter 509;" therefore these requirements apply only after a license or permit has been issued. However, applicants may use this

guidance to gain insight into the regulatory and statutory requirements with which they must comply once they receive a license or permit.

B. Crew Requirements

> *§ 460.9 Informing crew of risk. If a vehicle will not be government certified for human spaceflight by launch, the ~~An~~ operator must inform in writing any individual serving as crew that the United States Government has not certified the launch vehicle and any reentry vehicle as safe for carrying ~~flight crew or space flight participants~~occupants. An operator must provide this information –*
>
> *(a) Before entering into any contract or other arrangement to employ that individual as a crewmember: or*
>
> *(b) For any employed crew member ~~employed as of December 23, 2004~~, as early as possible and prior to any launch in which that individual will participate as crew.*

To comply with the regulatory requirements of § 460.9, if a vehicle is not human spaceflight certified, an operator must inform each non-government crew ~~-~~member in writing of the following, per the timeline requirements listed above:

> "The United States Government has not certified the [launch vehicle, ~~and any~~ reentry vehicle, or integrated vehicle, as applicable] as safe for carrying flight crew or space flight participants."

~~If applicable, A~~a launch or reentry operator must provide this statement to the crewmember before entering into any contract or other arrangement to employ that individual. If any crewmember is employed prior to the company being issued a license, this statement must be provided to the crewmember as early as possible and prior to any launch.

Although Congress has charged the FAA with certificating aircraft, it has not provided the agency the authority to certificate launch or reentry vehicles.~~;~~ NASA however, does exercise its own independent certification authority to standards that meet FAA human spaceflight requirements, and provides consultation to the FAA in support of commercial licensing. Congress has authorized AST to issue licenses or permits for the operation of launch and reentry vehicles. License and permit holders must be capable of launching (and reentering) without jeopardizing public health and safety and the safety of property. When applicable, ~~T~~the non-certification statement informs the crew that the FAA's oversight responsibilities related to the licensing or permitting process are intended to protect the public and do not extend to the safety of crew or space flight participants. In addition to providing the non-certification statement, operators are encouraged to explain that the statement means the U.S. government does not ensure the safety of flight crew,

Commented [A2]: Should not apply to government astronauts. Licensees are required to sign reciprocal waivers with their customers and consistent with 51 USC 50914(b), NASA astronauts need not sign waivers of claim against USG contractors/subcontractors as the government assumes liability.

Commented [A3]: Certification may be done for a combination of LV and RV/RLV.

Commented [A4]: This does not add additional context, it is just restating 460.9.

Commented [A5]: This will not be the case upon expiration of the learning period assuming HSF licensing requirements are added to include occupant safety.

~~government astronauts,~~ or space flight participants (individually and collectively, "occupants").

Commented [A6]: Though FAA does not, "U.S. government" includes NASA which IS responsible for ensuring astronaut safety.

During pre-application consultation, the FAA will educate applicants about the informed consent regulations for the crew. The FAA recommends that the documentation used to verify compliance include the crew member signature block and the date signed. Appendix B provides an example of an acceptable consent format covering the minimum information required to comply with § 460.9.

C. Space Flight Participant Requirements

An operator must inform each space flight participant of the risks of launch and reentry to comply with § 460.45. The regulations are silent about what language an operator must use in their discussions and documentation, but whatever language is used, the space flight participant must attest they understand the risks. Appendix C provides an example of an acceptable format covering the minimum information required to comply with § 460.45. The following offers guidance regarding information the operator must provide to space flight participants, including the risk of launch and reentry, level of technical detail, non-certification statement, human space flight safety record, vehicle safety record, request for additional information about accidents and incidents, oral questions, minimum age of a space flight participant, electronic signatures, compensation restrictions, and documentation. FAA reporting requirements are explained for operator awareness.

1. Risk of Launch and Reentry

> *§ 460.45 (a) Before receiving compensation or making an agreement to fly a space flight participant, an operator must satisfy the requirements of this section. An operator must inform each space flight participant in writing about the risks of the launch and reentry, including the safety record of the launch or reentry vehicle type. An operator must present this information in a manner that can be readily understood by a space flight participant with no specialized education or training, and must disclose in writing—*
> *(1) For each mission, each known hazard and risk that could result in a serious injury, death, disability, or total or partial loss of physical and mental function;*
> *(2) That there are hazards that are not known; and*
> *(3) That participation in space flight may result in death, serious injury, or total or partial loss of physical or mental function.*

An operator must inform space flight participants in writing about the risks of the launch and reentry, including known hazards and the potential for unknown hazards. The operator must identify the risks and hazards that could result in serious injury, death, disability, or total or partial loss of physical and mental function to the space flight participant and may do so with a hazard analysis. Section C.2 (Level of Technical Detail) provides guidance on the level of detail that would satisfy § 460.45.

Commented [A7]: This language is consistent with the term "casualty." While occupants may be exposed to industrial hazards on the ground, the primary risk is due to hazards inside the vehicle, particularly during flight when failure consequences are in many cases catastrophic. *Note that occupant safety risk exposure may, for orbital vehicles, extend beyond the period of public safety responsibility—this could be acceptable for an occupant safety assessment without driving a change to license/permit scope, but on-orbit risks also need to be evaluated.*

Additionally, neither the Statute nor part 460 defines the term "vehicle type." In this policy, the term 'vehicle type' means vehicles similar in design and structure as licensed or permitted by the FAA. For instance, SpaceShipOne and SpaceShipTwo are different vehicle types, as are the Mercury, Gemini, and Apollo capsules. The Shuttle vehicles are

considered the same vehicle type. Safety Record Criteria #7 in Appendix A discusses the use of "vehicle type" in the vehicle safety record. In this document, the terms "safety record of the launch or reentry vehicle type" and "vehicle safety record" are interchangeable.

Rationale: The preamble to part 460 [1] states that because § 460.45(a)(1) *"requires that an operator inform each space flight participant of the known hazards and risks that could result in a serious injury, death, or disability, the FAA anticipates that a hazard analysis focusing on keeping the space flight participant alive will be conducted by the operator to identify these hazards."*

2. Level of Technical Detail

In carrying out § 460.45, an operator must present technical information in a manner that ensures the space flight participants are informed of the risks of the launch or reentry and that those risks can be readily understood with no specialized education or training. The operator is not required to provide information that would violate export control regulations or disclose proprietary information. The operator is only required to describe hazards, risks, and technical data at a general system level, as necessary to provide insight as to potential safety impacts. For example, if a hazard exists in the turbo pump, the operator may state only that the hazard exists in the propulsion system. The risks associated with the stated hazard may be described generically as catastrophic (see Appendix A, #14). The operator may provide additional information at a more detailed level.

Commented [A8]: FAA should provide guidance on means of compliance to express individual risk/probability of occupant casualty in terms a layperson can understand and compare. One suggestion is to quantify risk as 1 in [#] which may be compared to the acceptable individual risk limit for public on the ground (1 in 1,000,000) and casualty statistics from early aviation and high risk recreational activities (e.g., SCUBA, skydiving, etc.). Attention must be given to the fact that this is a nascent industry and accurate risk comparison requires a statistically significant number of flights versus a small sample set of analytical data using predicted failure rates. Any effort to define a standard methodology for presentation of risk should involve significant industry participation.

Rationale: As described in preamble [1] of the human space flight regulations, information provided at the general system level satisfies the intent of the regulation to "ensure individuals on board are aware of the risks associated with a launch or reentry." During the Human Space Flight Rulemaking process [1], the FAA received public comment that a detailed disclosure would violate export control regulations and cause the release of proprietary information. In the preamble [1], the FAA agreed with the public comment and stated that it "will require only a general system description. An operator only needs to disclose, for example, that a propulsion system exploded, not the details of how the explosion occurred." Furthermore, detailed descriptions and questions about the vehicle might conflict with the requirement of § 460.45(a) which requires the information to "be readily understood by the space flight participant with no specialized education or training." An operator may choose to provide additional information to ensure the space flight participants understand the risks.

3. Non-Certification Statement

§ 460.45(b) An operator must inform each space flight participant that the United States Government has not certified the launch vehicle and any reentry vehicle as safe for carrying crew or space flight participants.

To comply with § 460.45(b), if a vehicle is not human spaceflight certified, an operator must inform each space flight participant in writing of the following:

"The United States Government has not certified the launch vehicle and any reentry vehicle as safe for carrying flight crew or space flight participants."

Rationale: As described in Section B (Crew Requirements), this non-certification statement explains to the space flight participant that the FAA's licensing and permitting requirements are not intended to ensure occupant safety. The FAA is currently prohibited from regulating the safety of occupants, except in response to specific situations that resulted in occupant casualties or posed a high risk of causing casualties. Additionally, although Congress has charged the FAA with certificating aircraft, it has not provided the agency the authority to ~~certificate~~ certify launch or reentry vehicles. Accordingly, this provision cautions space flight participants not to expect the same level of safety from space travel as from air travel. As explained in Section C.11 (Documentation), under section 460.45(a), an operator must provide this non-certification statement in writing.

Commented [A9]: This will not be the case upon expiration of the learning period.

4. Human Space Flight Safety Record

§ 460.45(c) An operator must inform each space flight participant of the safety record of all launch or reentry vehicles that have carried one or more persons on board, including both U.S. government and private sector vehicles. This information must include—

(1) The total number of people who have been on a suborbital or orbital space flight and the total number of people who have died or been seriously injured on these flights; and

(2) The total number of launches and reentries conducted with people on board and the number of catastrophic failures of those launches and reentries.

Section 460.45(c) requires an operator to provide the safety record of all U.S launch and reentry vehicles that have carried humans on a suborbital or orbital space flight. The FAA maintains on its website the information referenced in § 460.45(c)(1) and (2) that an operator may use, but the operator is responsible for ensuring the accuracy of its data provided to the space flight participant. The FAA's website ~~will~~ contains information for

Commented [A10]: Add a link to the exact location where this information is kept on the website.

Commented [A11]: Beyond comparing the data currency to that on the FAA website, operators should not be expected to verify accuracy of the data as it would be inefficient for each operator to ensure FAA's accuracy for each SFP. FAA should be responsible for keeping this up to date and accurate. Perhaps add a stipulation that each operator must provide updated information on their own flight records within a certain time frame so that is easier for FAA to keep up to date.

both U.S. government and private sector[1] vehicles, categorized into orbital and suborbital flights (see Appendix D). The website ~~will~~ also documents the criteria (see Appendix A) used to derive the data.

The FAA recommends that an operator provides updated information proximate and prior to launch if there have been material changes to the safety record since the space flight participant provided written informed consent.

Rationale: The FAA believes it will have the most comprehensive human space flight safety record data and will share that data with the operators to aid in compliance and consistency. The preamble to part 460 [1] supports this policy and also gives notice to industry of its responsibility for the accuracy of the data: "*Although a database, whether developed by the FAA or commercially, may eventually be used by an operator to help fulfill the requirements of § 460.45, ultimately it is the responsibility of the launch vehicle operator to inform each space flight participant of that safety record."*

Events may unfold or new information discovered such that the risk may be higher than when the space flight participant originally gave consent. Providing an updated safety record proximate and prior to launch, ~~and~~ describing why they may not apply to occupant risk for the specific vehicle, or identifying any resulting changes in the probability of occupant casualty, will help ensure that space flight participants are aware of the most current risk.

Commented [A12]: Provide clarification of time flow and data currency as it relates to written informed consent and booking the revenue.

Commented [A13]: Should not assume that an update to the safety record from one operator impacts occupant risk for another. Similarly, there may be separation between different vehicles of the same operator.

5. Vehicle Safety Record

> *§ 460.45(d) An operator must describe the safety record of its vehicle to each space flight participant. The operator's safety record must cover launch and reentry accidents and human space flight incidents that occurred during and after vehicle verification performed in accordance with §460.17, and include—*
>
> *(1) The number of vehicle flights;*
>
> *(2) The number of accidents and human space flight incidents as defined by section 401.5; and*
>
> *(3) Whether any corrective actions were taken to resolve these accidents and human space flight incidents.*

The operator must describe its vehicle safety record to the space flight participant in accordance with § 460.45(d). An operator may follow the safety record criteria documented in Appendix A and apply it to their complete vehicle history to produce an acceptable vehicle safety record. An acceptable vehicle history would include both of the following (see Appendix D for an example):

[1] "Private sector" is the term used in the regulations. It is used synonymously with "commercial" for the purposes of this policy.

a. Operator's vehicle history (fleet history for the vehicle type) in which the space flight participant will launch or reenter, including both government and commercial launches or reentries. The vehicle history will include, at a minimum, the number of vehicle flights and the number of accidents and human space flight incidents.
b. Whether any corrective actions were taken to resolve any of the accidents or human space flight incidents.

The FAA will maintain on its website the safety record of each vehicle type across all operators (see Appendix D for an example), including its revision date.

Per § 460.45(d)(3), if asked about corrective actions taken after an accident or incident, the operator needs to provide only the nature of its corrective action (e.g. that the turbo pump was redesigned, not that there was a material change in the impeller blade). Just as in the human safety record, after the space flight participant provides consent, the FAA recommends that the operator update the space flight participant of material changes in the risk or safety records before flight.

With regard to vehicle verification, verification flights are identified by the operator in its license or permit application to satisfy § 460.17 verification program requirements. The operator's verification program demonstrates the integrated performance of the vehicle's hardware and any software in an operational flight environment before allowing space flight participants on board during a flight. The FAA does not require an operator to include developmental testing in the vehicle safety record if it occurs prior to the vehicle verification. If the operator removes the vehicle from verification testing or operational flights for additional development testing, those tests are not required to be included in the vehicle safety record, but any change must undergo a subsequent verification program. Prior vehicle safety data should be evaluated for inclusion based on the significance of the change(s) Also called out in § 460.17 is the requirement that verification must include flight testing. The FAA will review and approve the verification flights identified in the operator's verification program on a case-by-case basis. The operator must conduct all envelope expansion flights and at least one flight in the full mission profile before flying space flight participants. These flights can be one and the same.

Rationale: A vehicle safety record that includes the operator's fleet history of a specific vehicle type provides the space flight participant with an understanding of the entire vehicle safety record and associated risks. Providing the safety record meets the intent of § 460.45(a) to *"inform each space flight participant in writing about the risks of the launch and reentry, including the safety record of the launch or reentry vehicle type."*

Utilizing the FAA safety record criteria when calculating the vehicle safety record will result in consistent reporting for all operators. There may be other acceptable methods of

Commented [A14]: (Multiple places through paragraph 6) Update to incorporate updated mishap terminology in Part 401.

Some prior accidents (for example, impact outside the nominal hazard area or damage to property on the ground) may not be relevant to occupant risk. Should narrow down to mishaps/categories applicable to the occupant hazard analysis.

Commented [A15]: Link to exact location on the website

Commented [A16]: FAA should review the safety record on a monthly basis to assure currency..

Commented [A17]: Clarify if "those tests" indicate the original verification testing and operational flights or the subsequent development and re-verification tests.

calculating the vehicle safety record. The same rationale for providing updated vehicle safety record information is discussed in Section C.4 (Human Space Flight Safety Record).

Because initial review of this material with the space flight participant may be done well in advance of the actual spaceflight, the operator should provide updated information proximate and prior to launch if there have been material changes to the vehicle safety record since the space flight participant provided written informed consent.

With regard to describing the corrective actions taken after an accident or incident, the FAA received public comment from industry with concerns that *"describing corrective actions could require the disclosure of proprietary data and company secrets."* The FAA agreed with the concern and in the preamble [1] stated that the FAA *"will not, as originally proposed, require an operator to also describe what corrective actions were taken."* The preamble further clarified the operator only needs to describe accidents and incidents *"…if a space flight participant asks and then only at the system level."* It is acceptable if the operator provides information beyond the general systems level as long as it does not violate export control regulations.

6. Request for Additional Information about Accidents and Incidents

> *§ 460.45(e) An operator must inform a space flight participant that he or she may request additional information regarding any accidents and human space flight incidents reported.*

An operator must inform space flight participants that they may request additional information about any accident or human space flight incident as disclosed in compliance with § 460.45(d). If asked, the operator may address failures at a general system level. The preamble [1] states "*The FAA expects space flight participants to come from all walks of life, with varying degrees of technical expertise and understanding. Congress requires that a space flight participant be informed of the risks, not that he or she acquire an understanding of basic engineering principles in order to understand that risk.*" The operator may provide additional information, as necessary, if it helps to explain the risk.

Rationale: By answering questions raised by space flight participants about accidents or human space flight incidents, the operator provides space flight participants with an opportunity to better understand the risks of space flight. Operators are not expected to provide failure summaries of another operator's vehicles due to a potential lack of insight into those failures.

7. Space Flight Participant Oral Questions

> *§ 460.45(f) Before flight, an operator must provide each space flight participant an opportunity to ask questions orally to acquire a better understanding of the hazards and risks of the mission, and each space flight participant must then provide consent in writing to participate in a launch or reentry. The consent must—*
> *(1) Identify the specific launch vehicle the consent covers;*
> *(2) State that the space flight participant understands the risk, and his or her presence on board the launch vehicle is voluntary; and*

Commented [A18]: Recommend that FAA define what is acceptable for "before flight" – does a vehicle operator satisfy this requirement if they engage and offer the SFP an opportunity to ask oral questions 1 year, 1 month, 1 week, or 1 hour in advance? Times may be appropriately different based on flight frequencies (of operators and industry).

It should be made clear that payment is not contingent on meeting this requirement (payment is predicated on a written disclosure, not oral) and the FAA recognizes that operator responses to SPF oral questions are not grounds for a mandatory refund if the SPF does not like the response(s). This is a contractual matter between the operator and the SFP.

(3) Be signed and dated by the space flight participant.

Prior to space flight participants giving written consent, an operator must provide an opportunity for the space flight participants to ask oral questions to acquire a better understanding of the hazards and risks of the mission. The discussion does not have to occur if the space flight participants decline the opportunity to ask questions. The questions may be in-person or remote (e.g. phone, video chat, etc.). If asked, the operator may address questions at a general system level. The operator may provide additional information, as necessary, if it helps to explain the risk. While there is no requirement to document the nature of the questions asked, operators are encouraged to incorporate that information into their informed consent presentations to enhance risk information provided to space flight participants.

Rationale: Under § 460.45(f), the opportunity to ask questions must take place before flight and before the space flight participant provides written consent. As described in the preamble [1], *"The FAA believes that an opportunity to ask questions allows a space flight participant a chance to get clarification on any information that may be confusing or unclear… In addition to receiving informed consent in writing from a space flight participant, this requirement serves as another 'cognizance test' or affirmation that the space flight participant understands what he or she is getting into before embarking on a mission. An operator must provide an opportunity for an oral discussion; the discussion does not have to occur if the space flight participant declines it."* To address export control regulation concerns and propriety information disclosure, operators may answer the questions *"at the system level."*

Commented [A19]: The provision for a SFP to ask oral questions before providing written consent ignores the probable timeline of an SPF purchase, training, medical exam, etc. There are likely more oral questions later in the process. An initial upfront "any questions" phone call at the time of transmission of the contract with attached disclosures, easily meets this requirement, as well as an included written statement that the SFP had the opportunity to ask oral questions. This could occur years before the actual flight.

8. Minimum Age of a Space Flight Participant

§ 460.45(f) (3) Be signed and dated by the space flight participant.

The FAA recommends that a space flight participant be at least 18 years old to participate in a launch or reentry, even if the participant has parental consent.

Rationale: Due to the risks involved with spaceflight, the FAA recommends that a space flight participant be at least 18 years old to participate in a launch or reentry, even if the participant has parental consent.

9. Electronic Signature

§ 460.45(f) (3) Be signed and dated by the space flight participant

For the purpose of documenting informed consent, electronic formats, including digital signatures or scanned copies of signatures on paper, are acceptable to the FAA.

Rationale: Industry inquired if electronic signatures are acceptable; the FAA responded that they are acceptable, as documented in an AGC legal interpretation memorandum to AST [2] "The regulatory text of § 460.45(f) does not state whether the signed writing it requires must be expressed in a paper or electronic format…Accordingly, we conclude that the signed writing required by §460.45(f) may be made in either of these formats."

10. Compensation Restrictions

> *§ 460.45(a) Before receiving compensation or making an agreement to fly a space flight participant, an operator must satisfy the requirements of this section.*

An operator must obtain the space flight participant's informed consent before receiving compensation or making an agreement to fly. Compensation for participating in a launch or reentry is not defined in regulation or statute. The FAA does not consider refundable deposits for a future space flight to be compensation or an agreement to fly. An operator may also accept compensation to screen the space flight participant for eligibility, or provide training, before proceeding to make an agreement to fly. Operators are encouraged to explicitly represent when compensation is accepted or an agreement to fly is made for participation in a launch or reentry.

Although these regulations do not apply to an applicant, the applicant must become compliant upon issuance of its license or permit. During pre-application consultation, the FAA will use this guidance to help applicants understand the regulatory and statutory requirements with which they must comply once they receive a license or permit.

Because the terms of 460.45 may be met well in advance of the actual spaceflight, the operator may provide SFPs with updates to the materials required for informed consent and answer any additional questions in a timeframe close to the actual launch. -Such updates are not subject to the compensation requirements of 460.45(a)

Rationale: Satisfying the requirements of § 460.45 ensures that the space flight participant understands the hazards and risks of launch or reentry before committing to the flight. Scenarios exist where an exchange of money may not constitute compensation. For instance, initial monies may be refundable or used as compensation for medical screening, training, and other space flight-related experiences. As discussed in the applicability section above, the regulations only apply to licensees or permittees; therefore, the compensation requirements apply once the FAA grants a license. In the case of a non-paying space flight participant, once the FAA grants a license or permit only "the agreement to fly" component of §460.45(a) requires the operator to follow the informed consent regulations.

Commented [A20]: Does this mean that an operator MAY accept compensation or make an agreement to fly prior to receiving a license/permit? Otherwise, Part 460 is part of the license application and therefore applies to applicants, even if implementation occurs later on (such as during the application review period). Suggesting that compliance be associated with issuance of a license or permit ignores the fact that those are often issued close to launch, leaving little time to "become" compliant.

Commented [A21]: This suggests that a space flight participant may commit to flight and provide compensation prior to license issuance.

11. Documentation

Operators may provide information required to be in writing in either paper or electronic format. Appendices C and D provide examples of acceptable forms for providing the information required to by § 460.45. Information that must be provided in writing includes:

- § 460.45(a) Risks of the launch and reentry
- § 460.45(a) Safety record of the launch or reentry vehicle type
- § 460.45(a)(1) Each known hazard and risk that could result in a serious injury, death, disability, or total or partial loss of physical and mental function
- § 460.45(a)(2) That there are hazards that are not known
- § 460.45(a)(3) That participation in space flight may result in death, serious injury, or total or partial loss of physical or mental function
- § 460.45(b) Non-certification statement (as applicable)
- § 460.45(c) Description of human space flight safety record
- § 460.45(c)(1) Total number of people who have died or been seriously injured
- § 460.45(c)(2) Total number of launches/reentries and catastrophic failures
- § 460.45(d) Description of vehicle safety record
- § 460.45(d)(1) The number of vehicle flights
- § 460.45(d)(2) The number of mishaps relevant to ~~accidents and~~ human space flight ~~incidents~~
- § 460.45(d)(3) Whether any corrective actions were taken
- § 460.45(f) Consent (by the space flight participant) (1) Identifies the specific launch vehicle that the consent covers; (2) States that the space flight participant understands the risk, and his or her presence on board the launch vehicle is voluntary; and (3) Is signed and dated by the space flight participant.

Although an operator is not required to document that it notified the space flight participant that he or she may request additional information regarding any accidents and human space flight incidents reported (§ 460.45(e)) or that it provided the space flight participant with an opportunity to ask questions orally to acquire a better understanding of the hazards and risks of the mission (§ 460.45(f)), doing so will simplify demonstration of compliance.

In accordance with § 417.15, § 431.77, or § 437.87, informed consent records are required to be retained until the latest of either (1) the completion of licensed activities or,

(2) if a launch or reentry accident or incident occurs, the completion of any Federal investigation and the FAA advises the licensee that there are no further requirements to retain the records. Per § 405.1 (Monitoring of licensed, permitted, and other activities) Federal officials may choose to observe oral briefings, as these discussions are not required to be documented and retained.

An operator's written disclosures do not have to be submitted to the FAA. Informed consent documentation is a post-licensing requirement and not part of an application.

12. FAA Reporting Requirements

> *51 U.S.C. §50905(b)(5)(A) requires "the Secretary has informed the space flight participant in writing of any relevant information related to risk or probable loss during each phase of flight gathered by the Secretary in making the determination required by section 50914(a)(2) and (c);*

While not an operator responsibility, operators should be aware Congress has directed the FAA by statute to inform space flight participants in writing of any relevant information related to risk or probable loss when making the Maximum Probable Loss (MPL) determination (section 50914(a)(2) and (c)).

Commented [A22]: Per Part 440, MPL calculations apply to 3rd party individuals and property, and expressly exclude spaceflight participants, so this would not be relevant.

D. References

[1] Human Space Flight Requirements for Crew and Space Flight Participants, Final Rule, 71 FR 75616 (Dec. 15, 2006) ("Human Space Flight Rule").

[2] Legal Interpretation, Memorandum to Glenn Rizner from Mark W. Bury, Assistant Chief Counsel for International Law, Legislation, and Regulations, AGC-200, June 10, 2014.

[3] Recommended Practices For Human Space Flight Occupant Safety, Version 1.0 August 27, 2014, Federal Aviation Administration.

E. Appendices

Appendix A: Safety Record Criteria

The FAA will use the safety record criteria listed below when developing the human space flight safety record. An operator following these safety record criteria when developing its vehicle safety record will produce an acceptable account. An operator is not required to use these provided safety record criteria; the operator has the option to develop comparable safety record criteria. Safety inspections may include verification of the consistent use of safety record criteria (or operator developed criteria) in deriving the safety records.

1. The human space flight safety record only includes launch and reentry vehicle flights during which a human was on board. The vehicle safety record includes both ~~manned~~ crewed and uncrewed~~manned~~ flights of launch and reentry vehicles designed to carry humans.

   Rationale: While the human space flight safety record requirement, § 460.45(c), specifies counting only human-occupied launch and reentry vehicles, the vehicle-specific requirement in § 460.45(d) does not contain this restriction. The vehicle-specific information, whether ~~manned~~ crewed or not, is important to the space flight participant to fully understand the risks and hazards.

2. Licensed or permitted launches and reentries, as well as launches and reentries conducted by and for the U.S. government, count in the human space flight safety record and vehicle safety record.

   Rationale: This criterion addresses the need to present only data that is relevant to the space flight participants. Non-licensed activities, such as development tests and glide flights under an airworthiness certificate, will not be counted because of the subjective nature in determining applicability. A safety record that accurately conveys the risks of launch and reentry should consist of all licensed or permitted activities and government launches and reentries that "would have been" licensed or permitted, had they been conducted by the private sector.

3. ~~Manned~~ Crewed U.S. Government launches to space or reentries from space are counted in the human space flight safety record.

   Rationale: This criterion provides guidance on how the FAA will track U.S. government-vehicle operations in the human space flight safety record, even though operations conducted by and for the U.S. Government are not licensed or permitted by the FAA. This criterion includes ~~manned~~ crewed flights intended for space, including but not limited to, the X-15, Mercury, Gemini, Apollo, and Space

Shuttle programs, but ~~will~~ excludes flights not intended for space, such as the lunar lander test program and aircraft with rocket-assisted capabilities.

4. Foreign launches and reentries (those not FAA licensed or not conducted by the U.S. government) ~~will~~ are not ~~be~~ counted in either safety record.~~,~~ ~~unless accurate launch and re-entry information is available. For example, if a bilateral agreement to share safety data exists between the FAA and the foreign government or entity, accurate information may be available.~~

   Rationale: According to the preamble [1]: *"The FAA did not propose to require disclosure of foreign [government or private] launch or reentry accidents because the information may not always be publicly available and its accuracy will be difficult to verify."* If the FAA has a bilateral agreement to share space flight safety data with a foreign government or entity, access to accurate launch and reentry information may be available; if so, it may apply to the human space flight safety record.

5. The human space flight safety record includes any flight with a human on board regardless if it occurred before, during, or after vehicle verification.

   Rationale: This criterion clarifies that even though the vehicle safety record only includes flights during and after vehicle verification, all ~~manned~~ crewed flights are included in the human space flight safety record. Verification flights are identified by the operator in its license or permit application to satisfy§ 460.17, verification program requirements.

6. The vehicle safety record includes all flights during and after vehicle verification regardless of whether any humans were on board.

   Rationale: The FAA clarified its position on the contents of the vehicle safety record in the preamble [1]: *"The FAA agrees that an operator need only disclose its safety record created during and after vehicle verification performed in accordance with § 460.17."* Verification flights are identified by the operator in its license or permit application to satisfy§ 460.17. The FAA does not require an operator to include developmental testing in their verification program.

7. Earlier vehicle types that predate the verification of the vehicle are not part of the vehicle safety record. In this policy, a vehicle type means vehicles similar in design and structure as licensed or permitted by the FAA.

   Rationale: Per the final rule preamble [1] the FAA agreed with the public comment: *"safety performance related to an earlier, experimental model is not directly relevant to a final, passenger-carrying model."* The FAA agreed with the commenter in principle, but the term 'model' is not defined in statute or

Commented [A23]: This hasn't been implemented, and the statement suggests potentially inconsistent application of data. In addition to data accuracy concerns, foreign flight records may not be relevant since there are no international industry standards and foreign government safety standards vary widely. Recommend continuing with U.S. only data.

regulation. The term 'vehicle type' is used in the commercial space regulations and statute, to describe vehicles similar in design and structure (e.g. SpaceShipOne and SpaceShipTwo are different vehicle types). Verification flights are identified by the operator in its license or permit application to satisfy § 460.17, verification program requirements.

8. The launch and reentry count as one flight for both safety records for orbital and suborbital missions.

   Rationale: To simplify reporting and avoid confusion, the FAA will count the launch and reentry phases as one in the safety record. From an informed consent perspective, the risk of the whole flight matters and not the specifics of the launch or reentry phase.

9. If there was intent to launch, ground-launched vehicles that do not leave the launch pad or ~~,~~ runway ~~under own power,~~ or air-launched vehicles that do not have a successful ignition, do not count as a flight in the safety records unless a mishap occurs. If a mishap occurs, the human space flight and vehicle safety record covers the timeframe from when the occupants are (or would be) exposed to vehicle hazards prior to flight until after landing when they are no longer exposed to vehicle hazards.

   Rationale: This criterion includes accidents occurring on the ground, but avoids counting launch recycles as flights in both safety records. Per the preamble [1],

   "The FAA is including accidents occurring on the ground because those are relevant to the risks a space flight participant faces. Accordingly, if a launch vehicle exploded upon ignition while on the ground, the explosion would have to be included as part of the vehicle safety record." The FAA asserted this same philosophy in its Recommended Practices for Human Space Flight Occupant Safety [3]. For example, the Apollo 1 fire, which occurred with crew on board during a launch pad test, would not count in the human space flight record because there was no intent to launch.

10. A flight with intent to launch that fails to complete its nominal flight profile is counted as a flight in both safety records.

    Rationale: This criterion includes any vehicle that ignites its rocket and does not attain its nominal altitude or orbit. If the vehicle does not complete the nominal flight profile (e.g., an abort), the occupants are exposed to risk; therefore the flight will count in the human space flight and vehicle safety records.

11. Regarding hybrid launch systems, only occupants on board the rocket-powered, space-bound vehicle count toward the safety record.

Commented [A24]: Includes horizontally launched vehicles that take off directly from a runway vs. on a carrier aircraft.

Commented [A25]: While an abort is an obvious example of risk exposure, impacts of an off-nominal altitude or orbit should be clarified terms of resulting occupant hazards (i.e., suborbital vehicle collision in uncleared airspace, landing in unplanned location/conditions, orbital vehicle collision with other space objects).

Rationale: The carrier vehicle is the first stage of the launch system but only the rocket-powered vehicle is designed to go into space. As required by § 460.45(c) only "people who have been on a suborbital or orbital space flight" will count in the safety record.

12. The human space flight safety record includes flight crew, government astronauts, and space flight participants who suffered a serious or fatal injury from the time they are exposed to vehicle hazards prior to flight, until after vehicle landing when they are no longer exposed to vehicle hazards.

    Rationale: Section 460.45(c)(1) requires disclosure of deaths and serious injury. The FAA's Recommended Practices For Human Space Flight Occupant Safety [3] defined a minimum medical timeframe adopted by this policy: "the occupants of commercial human space flight vehicles should not experience an environment that would cause a serious injury or fatality, from the time they are exposed to vehicle hazards prior to flight until after landing when they are no longer exposed to vehicle hazards."

13. Title 49 CFR 830.2 will be used for the definition for serious injury.

    Rationale: 14 CFR 401.5 sets forth the definitions for Chapter III of Title 14 of the Code of Federal Regulations and defines a "launch accident," in part, as "an event that causes a fatality or serious injury (as defined in 49 CFR 830.2)." The same definition of "serious injury" will apply to part 460. Pursuant to 49 CFR 830.2: *"serious injury means any injury which: (1) Requires hospitalization for more than 48 hours, commencing within 7 days from the date of the injury was received; (2) results in a fracture of any bone (except simple fractures of fingers, toes, or nose); (3) causes severe hemorrhages, nerve, muscle, or tendon damage; (4) involves any internal organ; or (5) involves second- or third-degree burns, or any burns affecting more than 5 percent of the body surface."*

14. "Catastrophic failure" from § 460.45(c) for the purpose of determining a safety record means a failure causing death or serious injury to the people on board. Launch or reentry aborts, regardless of the cause, are not counted as a catastrophic failure unless death or serious injury occurs.

    Rationale: While the regulations do not define catastrophic, Advisory Circulars 437.55-1 and 431.35-2A provide guidance on how to define catastrophic in in the context of distinguishing the different types of outcome to public safety. The definition provided above has been modified to address occupant safety. While there are numerous ways to define a catastrophic failure, ultimately the space flight participant's risk comes down to death or serious injury. An abort from an exploding rocket may be a very significant experience, but by itself may not be catastrophic to the space flight participant who is not injured by the event.

15. Safety critical aborts are considered a human space flight incident in the vehicle safety record.

Rationale: Safety critical aborts are considered incidents because they pose a high risk to the occupant and therefore meet the definition in § 401.5 *"Human space flight incident means an unplanned event that poses a high risk of causing a serious or fatal injury to a space flight participant or crew."* Additionally, safety critical is defined in § 401.5 as *"essential to safe performance or operation."* Non-safety critical aborts such as a carrier vehicle returning to the launch site due to high winds does not count as a human space flight incident because a system did not malfunction requiring safety critical action to prevent serious or fatal injury. Aborts resulting from the activation of an escape system~~,~~ to separate from an exploding rocket, are safety critical, pose a high risk to the occupants and even if successful, are considered a human space flight ~~incident~~mishap. The same is true of aborts resulting from activation of a flight safety system for the purpose of protecting public safety, even if the vehicle malfunction did not pose a hazard to occupants.

Appendix B: Example of Crew Documentation

Example of acceptable documentation to comply with section 460.9 (Crewmember):

NON-CERTIFICATION DISCLOSURE TO THE CREW

(Crewmember),
As required by 14 CFR §460.9 we are informing you:
"The United States Government has not certified the launch vehicle and any reentry vehicle as safe for carrying ~~flight crew or space flight participants~~occupants."
(Company Name)

_____
CREWMEMBER SIGNATURE

DATE

Appendix C: Example of Space Flight Participant Consent

Example of acceptable documentation to comply with section 460.45 (Space flight participant):

INFORMED CONSENT FOR SPACE FLIGHT PARTICIPANTS ACKNOWLEDGEMENT OF RECEIPT

Company Name:
Vehicle Name:

I ACKNOWLEDGE that before paying compensation or agreeing to fly on [INSERT THE SPECIFIC LAUNCH OR REENTRY VEHICLE THE CONSENT COVERS], I received and reviewed the following information from [INSERT OPERATOR NAME].

INFORMATION

(1) The following are known hazards and risks that could result in a serious injury, death, disability, or total or partial loss of physical and mental function. [INSERT or ATTACH: LIST OF EACH KNOWN HAZARD AND RISK] (____) INITIAL EACH HAZARD AND RISK

(2) There are hazards that are not known. (____) INITIAL

(3) My participation may result in my death, serious injury, disability, or total or partial loss of physical and mental function; (____) INITIAL

(4) The United States Government has not certified the launch vehicle and any reentry vehicle as safe for carrying ~~crew or space flight participants~~occupants. (____) INITIAL

(5) I have received from [INSERT OPERATOR NAME] Appendix A (Human Space Flight Safety Record) to this Acknowledgment of Receipt, and have been informed of the safety record of all launch and reentry vehicles that have carried one or more persons on board, including both U.S. government and private sector vehicles, which included (i) the total number of people who have been on a suborbital or orbital space flight and the total number of people who have died or been seriously injured on these flights and (ii) the total number of launches and reentries conducted with people on board and the number of catastrophic failures of those launches and

reentries. (____) INITIAL [PROVIDE **APPENDIX A** TO THIS AGREEMENT]

(6) I have received from [INSERT OPERATOR NAME] Appendix B (Vehicle Safety Record) to this Acknowledgment of Receipt, which describes the safety record of [INSERT VEHICLE NAME], as detailed at Appendix B to this Acknowledgment of Receipt. This description include~~d~~s the number of any launch and reentry accidents and human space flight incidents that occurred during and after vehicle verification ~~performed~~, and include~~d~~s: the number of vehicle flights; the number of accidents and human space flight incidents; and whether any corrective actions were taken to resolve these accidents and human space flight incidents. (____)
INITIALS [PROVIDE **APPENDIX B** TO THIS AGREEMENT]

(~~7~~8) I understand that I may request additional information regarding any accidents and human space flight incidents reported. (____) INITIALS

(~~8~~9) I have been provided with the opportunity to ask questions orally to acquire a better understanding of the hazards and risks of this mission. (____) INITIALS

ACKNOWLEDGE OF RECEIPT

I knowingly consent to participate in the launch and/or reentry of the [INSERT THE SPECIFIC LAUNCH OR REENTRY VEHICLE THE CONSENT COVERS] vehicle. I understand the risk and my presence on board is voluntary.

_____
SPACE FLIGHT PARTICIPANT

_____
DATE

Appendix D: Example of Safety Record

Example of acceptable documentation to comply with section § 460.45(c) and § 460.45(d).

Human Space Flight Safety Record

§ 460.45(c) An operator must inform each space flight participant of the safety record of all launch or reentry vehicles that have carried one or more persons on board, including both U.S. government and private sector vehicles. This information must include—

(1) The **total number of people who have been on a suborbital or orbital space flight** and the **total number of people who have died or been seriously injured** on these flights; and

(2) The **total number of launches and reentries conducted with people on board** and the **number of catastrophic failures of those launches and reentries.**

Launch type	Total # People on Space Flight	Total # People Died or Seriously Injured	Total # of Human Space Flights	Total # of Catastrophic Failures
Orbital (Total)	**X**	**X**	**X**	**X**
Suborbital (Total)	**X**	**X**	**X**	**X**
Total	**X**	**X**	**X**	**X**
Space flight information was last updated MM/DD/YYYY				

Commented [A26]: Data on casualties/failures could be more useful in ratio form ((# casualties/total # people and # catastrophic failures/total # of human space flights) to enhance perspective on risk.

Commented [A27]: Total people/casualties is less relevant to spaceflight participant safety than the number of human flights and failures. As with risk calculations for aircraft, it's assumed that catastrophic failures result in loss of all onboard, but individual occupant risk is independent of the number of occupants. Perceived risk for the entire industry is unnecessarily inflated, weighted more heavily by vehicles with more occupants (STS crew size ranged from 2 to 8 but both failures involved 7 casualties)--is this really useful for informed consent? Occupants need only be aware of risk to themselves, though collective occupant risk may be useful for liability determination purposes.

Vehicle Safety Record

§ 460.45(d) An operator must describe the safety record of its vehicle to each space flight participant. The operator's safety record must cover launch and reentry accidents and human space flight incidents that occurred during and after vehicle verification performed in accordance with §460.17, and include—

(1) **The number of vehicle flights;**
(2) **The number of accidents** and **human space flight incidents** as defined by section 401.5; and
(3) Whether any corrective actions were taken to resolve these accidents and human space flight incidents.

Operator Provided *Vehicle Safety Record*			
Operator A	**# of Vehicle Flights**	**# of Accidents***	**# HSF Incidents***
Vehicle Y	**X**	**X**	**X**
Vehicle flight information was last updated MM/DD/YYYY			
*The operator must indicate whether any corrective actions were taken to resolve these accidents and human space flight incidents.			

FAA Provided *Vehicle Safety Record Across All Operators*			
Launch type	**# of Vehicle Flights**	**# of Accidents**	**# HSF Incidents**
(+) Orbital			
(-) Suborbital	**X**	**X**	**X**
Vehicle X	X	X	X
Vehicle Y	X	X	X
Vehicle Z	X	X	X
…			
Vehicle flight information was last updated MM/DD/YYYY			

Commented [A28]: (for both Operator and FAA provided tables) Once there are enough flights to be statistically significant, this data could be summarized by a percentage of flights resulting in mishaps (relevant to human spaceflight risk).

Commented [A29]: (for both Operator and FAA provided tables) Combine and update consistent with new mishap definitions. Result should be limited to the number of mishaps relevant to human spaceflight risk (excluding public risk).