JSC 27472

Requirements for Submission of Data Needed for Toxicological Assessment of Chemicals to be Flown on Crewed Spacecraft

Human Health and Performance Directorate

Biomedical Research and Environmental Sciences Division

Toxicology Group; Environmental Sciences Branch

Biomedical Research and Environmental Sciences Control Board (BRESCB) Controlled

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National Aeronautics and Space Administration
Lyndon B. Johnson Space Center
Houston, Texas

NASA APPROVAL SHEET

Requirements for Submission of Data Needed for Toxicological Assessment of Chemicals to be Flown on Crewed Spacecraft

Human Health and Performance Directorate

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CHANGE HISTORY

Status	Revision No.	Change No.	Description	Release Date
Baseline	-		Baseline Change Summary: Initial Release as JSC 25607.	10/1994
Baseline	-		Baseline Change Summary: Assigned new document number.	09/1996
REVISION	A		Revision A Change Summary: Major revision of entire document.	03/1999
REVISION	A	2	Revision A, PCN 2 Change Summary: Updated links.	8/12/2003
REVISION	B		Revision B Change Summary: Added requirements for part numbers of all hardware sub-systems. Added statement citing potential inclusion of ECLSS assessments in HMST. Added request for battery chemistry data. Modified text concerning biological assessments.	6/25/2006
REVISION	C		Revision C (Approved at FACB, per SA-00616, dated 04/25/2018) Prepared By: Space Toxicology Group of the National Aeronautics and Space Administration Change Summary: Global revisions to reflect changes to NASA Programs and external requirements documentation. Update to information requirements descriptions and process descriptions throughout document.	07/31/2019
REVISION	D		Revision D (Approved at FACB, per SA-01844, dated 07/31/2019) Prepared By: NASA Toxicology Group Change Summary:	08/09/2019

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			Revision to update data submission requirements for batteries and capacitors per approval by the FACB, S&MACB, VCB, and GJOP Update to verification requirements for reflight items for clarity	
REVISION	E		Revision E (Approved at BRES CB, per SA-04481, dated 01/12/2022) Prepared By: NASA Toxicology Group Change Summary: Updates to accommodate new eHMST tool for ISS, provide clarification of timeline for assessments, and add exclusions for greases, hygiene items, and nuisance particles.	01/12/2022
REVISION	F		Revision F (Approved at BRES CB, per SA-06140, dated 07/19/2023) Prepared By: NASA Toxicology Group Change Summary: Updates to accommodate new eHMST tool for Exploration.	07/19/2023
REVISION	G		Revision G (Approved at BRES CB, per SA-06924, dated 04/02/2024) Prepared By: NASA Toxicology Group Change Summary: Updates to include qualifications for non-flight-specific records and removal of references to HazMat	04/02/2024

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1.0 INTRODUCTION

1.1 PURPOSE

Data on chemical and biological materials to be flown in the pressurized volumes of habitable spacecraft are needed by the National Aeronautics and Space Administration (NASA) Subject Matter Experts (SMEs) to assess the hazards to human health and life supporting hardware. Submittal of data required for hazard assessment of proposed flight materials (e.g. chemicals and biological agents) has been consolidated into a single electronic data submission tool (eHMST). This document describes the specific data needed for JSC Toxicology to assign Toxicity Hazard Level (THL) and how this integrates with assessments performed by other SMEs to define the Hazard Response Levels (HRLs). It outlines submission schedules and establishes requirements for the types and format of these data to ensure accurate and timely completion of the hazardous materials summary tables (HMSTs) which capture information from several different SMEs. Adherence to these submission schedules and requirements will help eliminate unnecessary delays or obstacles to the toxicological assessment and subsequent Safety Panel approval of materials for flight.

1.2 SCOPE

This document is invoked by the applicable safety review processes (e.g. SSP 30599, Safety Review Process and Multi-Purpose Crew Vehicle (MPCV) 70038, Orion MPCV Program Hazard Analyses Requirements). It, together with JSC 26895, Guidelines for Assessing the Toxic Hazard of Spacecraft Chemicals and Test Materials, facilitates the toxicological assessment of chemicals and test materials which are required elements of NASA safety review processes. Toxicity assessments and THL ratings are documented and communicated in the form of Toxicity Assessment Memoranda and/or HMSTs which are delivered to the hardware/payload provider for delivery to the safety panel via inclusion in Safety Data Packages (SDPs) and/or Hazard Reports. These safety panels are integral elements of the major space flight programs conducted by NASA and its domestic and international partners. Some examples of various safety panels with whom the JSC Toxicology team works in support of crewed space flight programs include:

1. The International Space Station (ISS) Safety Review Panel (ISRP) – oversees safety reviews for all ISS hardware/elements (inclusive of Contractor Furnished Equipment [CFE] and Government Furnished Equipment [GFE]), its ground support equipment, payload/science hardware, and visiting vehicles (denoted within SSP 30599 as “END ITEMS”).
2. The Multipurpose Crewed Vehicle Safety and Engineering Review Panel (MSERP), Joint Safety and Engineering Review Panel (JSERP), and Exploration Systems Directorate Safety and Engineering Review Panel (ESERP) – oversee safety review of issues related

to NASA exploration-class crewed space vehicles, off-world crewed habitats, related spacesuits, and planetary vehicles and the supporting European Service Module.

3. The Safety Technical Review Board (STRB) – Provides NASA oversight of safety review of issues related to commercially-provided crewed space vehicles and spacesuits.

1.3 RESPONSIBILITY AND CHANGE AUTHORITY

The JSC Space Toxicology Group, a part of the Biomedical Research and Environmental Sciences (BRES) Division within the Human Health and Performance (HHP) Directorate (SA), is responsible for preparation and maintenance of this document. Final approval of changes to this document resides with the BRES Control Board. The Space Toxicology Group, hereafter referred to as JSC Toxicology, is responsible for establishing, documenting, and maintaining technical and scientific aspects of the requirements listed in this document and JSC 26895, which are needed to facilitate toxicological assessment of chemicals to be flown for use in crewed spacecraft. Furthermore, JSC Toxicology is solely responsible for final assignment of THL ratings.

1.4 NASA TOXICOLOGICAL HAZARD ASSESSMENT

JSC Toxicology is responsible for performing toxicity assessments, assigning THL(s), and determining physical asphyxiation and/or confined space/first entry hazards. Other groups are responsible for assessing other hazards. Assessment of hazards associated with biological agents will be conducted by the JSC BioSafety Review Board (BRB) who will assign a BioSafety Level (BSL) according to JPR 1800.5, Biosafety Review Board Operations and Requirements. Assessment of materials flammability will be conducted by the JSC Materials and Processes Branch (ES4) who will assign a flammability hazard level (FHL) according to JSC 64825A, Guidelines for Assessing the Flammability Hazard of Spacecraft Chemicals and Test Materials. Assessment of the impacts of materials on Environmental Control and Life Support System (ECLSS) will be conducted by ECLS System Management & Engineering Support who will assign ECLS ratings according to JSC 66869, Guidelines for the Assessment of Chemicals and Materials for Impacts to Environmental Control and Life Support Systems and Habitable Volumes of Crewed Spacecraft. Assessment of radioactive materials will be conducted by the JSC Radiation Constraint Panel (RCP)/Radioactive Payloads Working Group (RPWG) which is an element of the NASA JSC Space Radiation Analysis Group (SRAG, SD2). HMSTs are composed of individual database records of payloads, system components, equipment, supplies, etc. that house chemical and/or biological hazards. The THL, BSL, and FHL define a combined HRL for each record. HMST records are used to support formal flight programs and/or safety reviews (both mission- and non-mission-specific) and subsequently used to build mission-specific flight data files[1] which are uploaded to space vehicles and to Mission Control consoles.

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1.5 APPLICABILITY

The requirements put forth by this document apply to items that house (or produce) liquids, gases, gels, greases, powders/particulates that are to be used in, transported to/through, or that may, through credible failure, enter into the habitable areas of United States (U.S.) spacecraft, non-U.S. spacecraft inhabited by U.S. crew members, space suits, or habitable areas of off-Earth habitats where U.S. crew members would be present now or in the future. This includes chemicals in hardware or payloads carried in or by any visiting spacecraft (visiting vehicles) to and from the ISS. These requirements apply during any mission phase (e.g., during launch and ascent, on-orbit utilization, storage, and return to Earth in a vehicle transporting humans). These chemicals may be included in, but are not limited to, items classified as contractor furnished equipment, government furnished equipment, International Partner cargo, payloads, system hardware, visiting vehicle hardware, materials science payloads, risk mitigation experiments, detailed/development test objectives, detailed supplementary objectives, and life science experiments. These requirements apply even to materials that are generally regarded by the public or other aerospace groups as non-toxic (e.g., water or compressed air) regardless of the hazard severity classification (e.g., marginal, critical, or catastrophic (refer to appropriate safety panel technical documents)) appended to the hardware/item by any safety panel.

These requirements apply to all materials contained in hardware and to chemical components that may be produced during operation of a payload/hardware or specifically identified off-nominal conditions associated with the payload/hardware. These requirements apply to generic medical kits but rarely crew hygiene kits (see exceptions below).

1.5.1 EXCEPTIONS

These requirements do not apply to flight hardware, vehicle structural components, or hygiene kits and medical kits that do not contain chemicals, or to nominal materials off gas products from hardware. Certain other categories of items may be tracked and/or assessed by JSC Toxicology but are exempt from requirements to submit data for toxicological assessments specified in this document. These include items such as food and potable water (which are not part of any experimental payload), items in crew preference kits, items classified as miscellaneous crew supplies, and items that never enter the habitable volume. Most crew hygiene items are also exempt per TOX-VR-2021-02, "Memorandum of understanding for crew hygiene items". Common greases (e.g. Braycote, Krytox, silicone greases, and synthetic hydrocarbon greases) that are applied on the ground prior to launch, used in standard lubricating amounts (< 1 g total), and inaccessible to crew in flight (internal to the hardware) do not require an HMST. Greases covered by this exclusion do not need to be identified. Per TOX-VR-2021-03, "Evaluation of Particles/Dusts in Habitable Spacecraft", chemically inert, non-sharp particles greater than 500 microns (0.5 mm) in size at a dispersed concentration less than 50 g/m3 are considered a nuisance hazard and do not require and HMST. Although data submittal

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is not required for these items, JSC Toxicology is required to assign the appropriate exemption code (e.g. “N” for items containing no chemicals/biologicals, “X” for items that may or may not contain chemicals but are exempt from assessment, or “E” for items that contain chemicals but are never located in the habitable volume of a space vehicle). Therefore, JSC Toxicology may request verification that items qualify for the above exemptions.

If an End Item Provider (EIP) is proposing to utilize only substances such as food, food additives, and/or potable water that may already be on-board a crewed vehicle or habitat during the course of mission-related operations, then the EIP shall declare this to the Safety Panel of record. At the discretion of the Safety Panel, toxicological assessment of these items may be waived and data submittal to JSC Toxicology is not required. If an EIP is proposing to utilize these on-orbit items in combination with other items being launched, the data submittal form will be completed, and the use of on-orbit water or pantry items will be noted in the brief summary of the experiment. Additional data for these on-orbit or pantry items are not required.

From a human health protection perspective, hazard levels, including THLs, are only applicable to crew members and passengers during space flight. Space flight, for the purpose of this document, is defined as any mission phase when the crew and/or passengers are isolated/sealed inside the habitable volume of a space vehicle and/or pressure “space” suit. This includes periods when the space vehicle may be within the atmosphere of a celestial body such as during prelaunch, ascent, decent, and post landing phases when the habitable volume is sealed and isolated from the outside atmosphere. While they may be used as a screening tool for ground handling, THLs are not applicable to any ground-based activity involving the assessed chemicals such as terrestrial transport and/or storage of chemicals and are not applicable to support safety assessment and protection of any personnel other than space crews during space flight. Other government bodies such as The U.S. Occupational Health and Safety Administration (OSHA) hold jurisdiction for regulation of chemicals and protection of humans in U.S. terrestrial settings.

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2.0 DOCUMENTS

2.1 VERB APPLICATION

This document adheres to the following verb application. The verb "shall" is used to indicate actions that are required. Statements that contain the word "should" are intended to be guidelines and/or suggested practices. Use of the verb "will" indicates a statement of fact and is not verified. The verbs "should" and "may" are used for stating non-mandatory goals.

2.2 APPLICABLE DOCUMENTS

The following documents include specifications, models, standards, guidelines, handbooks, and other special publications. The documents listed in this paragraph are applicable to the extent specified herein. Applicable documents consist of documents that contain provisions or other pertinent requirements directly related to and necessary for the performance of the activities specified by the document. Applicable documents for requirements mandated by a project, governed by SA and for SA or others, in terms of both activities and deliverables should be included in the Applicable list. Applicable documents shall contain true requirements that indicate a provision that is mandatory. All Applicable documents shall be the most current version, unless it is a version otherwise stated from a previous piece of hardware.

Document No.	Title
SSP 30599	Safety Review Process
SSP 51721	ISS Safety Requirements Document
MPCV 70038	Orion Multi-Purpose Crew Vehicle (MPCV) Program Hazard Analyses Requirements
JSC 26895	Guidelines for Assessing the Toxic Hazard of Spacecraft Chemicals and Test Materials
JPR 1800.5	Biosafety Review Board Operations and Requirements
JSC 64825A	Guidelines for Assessing the Flammability Hazard of Spacecraft Chemicals and Test Materials
JSC 66869	Guidelines for the Assessment of Chemicals and Materials for Impacts to Environmental Control and Life Support Systems and Habitable Volumes of Crewed Spacecraft

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2.3 REFERENCE DOCUMENTS

The following documents contain supplemental information to guide the user in the application of this document. These reference documents may or may not be specifically cited within the text of this document. Reference documents shall include any document that has been cited in the document with “Should”, “May”, “Will”, “As Applicable”, etc.

Document No.	Title
TOX-VR-2017-01	Evaluation of LiOH in Habitable Spacecraft
TOX-VR-2022-06	Memorandum of Understanding for Crew Hygiene and Personal Use Items in Spacecraft Carrying NASA Crew
TOX-VR-2022-05	Toxicological Assessment of Aldehyde Vapors in Spacecraft
TOX-VR-2023-01	Evaluation of Particles/Dusts in Habitable Spacecraft
TOX-VR-2023-02	Toxicological Assessment of Liquid Crystal Displays

3.0 END ITEM PROVIDER (EIP) RESPONSIBILITIES

3.1 WHO SHALL PROVIDE THE DATA AND TO WHOM

Any person or group (henceforth referred to as an End Item Provider or EIP) responsible for the development, construction, integration, and/or preparation of a flight article that contains items described above is/are responsible for supplying all necessary data for hazardous materials assessments to the data submittal portal described in Section 3.4, How the Data Shall Be Formatted and Submitted, of this document. The format and timeline for data submittals shall be in accordance with the guidelines described in this document.

An EIP point of contact (POC) will be responsible for providing information on chemicals in the payload/hardware and shall be available to answer specific questions as HMST records are created and as payloads are prepared for launch. Therefore, the EIP POC must be thoroughly familiar with the payload or equipment composition and function (e.g. a principal investigator, payload coordinator, or payload integration manager with this knowledge). Open communication and coordination are encouraged between the EIP and the Toxicologist assigned to provide a toxicity assessment. THL assignments and HMST development often require multiple iterative steps between the EIP and the Toxicologist. Open communication and coordination will ensure timely assessment of hazards and delivery of products to support the safety review deadlines and mission-related data deliveries.

3.2 WHAT SPECIFIC TYPES OF DATA ARE NEEDED

The EIP shall submit required data via the eHMST tool.

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3.2.1 INFORMATION REQUIRED FOR ASSESSMENTS

For all chemicals, the EIP shall provide:

1. The name, affiliation, phone number, and e-mail addresses of the EIP POC.
2. The hardware name, as it appears in the official NASA manifest system (Mission Integration Database Application System [MIDAS Prime] for ISS and the Electronic Stowage Assessment Tool (eSAT) for Exploration), of the experiment or hardware and of all subsystems that contain the chemicals/biologicals.
3. The part number exactly as it appears in the official NASA manifest system. If it has not yet been determined, this number should be provided as soon as it becomes available. This number will be required for completion of the final verification (Verification-2 [V-2]) of the HMST (described in Appendix B, The Toxicology Hazardous Materials Summary Table Development and Verification Process). Failure to provide this part number may result in unnecessary delays for hardware acceptance and launch processing.
4. A brief description of the hardware and/or of the experiment, including procedures such as mixing, heating/combustion, or other processing of materials which affects their composition or concentration.
5. The unofficial "targeted" mission number, if known. If unplanned or unknown, the EIP should list the flight as To Be Determined (TBD).
6. The locations (i.e., US Laboratory, Dragon, MPCV, etc.) during launch, on-orbit stowage, processing, and re-entry; if location within the ISS is unknown, broadly note USOS or ROS.
7. The number of items of each type (e.g. "one syringe" or "two vials") when there is a common failure mechanism that may lead to release of more than one item.
8. Designation of proprietary data.
9. Safety Data Sheets (SDS), if available (except for common chemicals).

3.2.2 INFORMATION NEEDED SPECIFICALLY FOR SOLUTIONS, GELS, MIXTURES, POWDERS, AND PARTICULATES

For liquids, solutions, gels, mixtures, powders, and particulates, the following additional data shall be provided:

1. The chemical identity of each component (for commercial undefined mixtures, e.g. sera, broths, and extracts, provide commercial identification, e.g. Hyclone FetalClone I fetal bovine serum).
2. The volume or weight of each separately contained portion of an item (e.g. 1.5 mL/syringe or 2 g/packet).

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3. The number of separately contained portions of each item to be flown (i.e. the number of identical samples, for example 10 kits or 2 containers).
4. The particle size range of powders and particulates (including plant seeds) as well as both the true and bulk (apparent) density of the material when available.
5. The potential of hydrogen (pH) of all solutions in launch, on-orbit, and landing configurations. Note any expected changes in pH due to on orbit activities and/or storage.
6. The identity and amounts of anticipated reaction products, if applicable.
7. A brief process description, especially if there is a configuration change due to on-orbit operations (Ops) (for example, 1 ml of fixative solution will be added to this sample during Operations).
8. The purity of polydimethylsiloxane (PDMS), polysiloxane, dimethicone, siloxane, and silicone fluids & lubricants as required to assess the material's volatile methyl siloxane content.

3.2.3 INFORMATION NEEDED SPECIFICALLY FOR GASES

For gases, the following additional data shall be provided:

1. The chemical identity and purity of each gas.
2. The concentration of each gas in a mixture.
3. The volume of the containment vessel.
4. The pressure and mass of the gas(es).

3.2.4 INFORMATION NEEDED SPECIFICALLY FOR COMBUSTION EXPERIMENTS OR EXPERIMENTS EMPLOYING ELEVATED PROCESSING TEMPERATURES

Combustion experiments may include those that involve thermal degradation and/or thermal processing of reactants, fuels, stock materials such as plastic used in printing processes, materials heated in a furnace, etc. in which elevated temperatures are employed. For these experiments, the following additional data shall be provided:

1. The identity, amount per sample, and number of samples of each material to be burned or thermally degraded.
2. If known, provide maximum temperature and duration of heating.
3. The composition of the pre-combustion atmosphere.
4. The anticipated combustion products and their amounts, if known.
5. The planned disposal method for combustion products after each test.
6. A description of the sample holders and containment systems during storage, during processing, and after processing.

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3.2.4.1 INFORMATION NEEDED SPECIFICALLY FOR METALS TO BE PROCESSED IN A FURNACE

For metals to be processed in a furnace during a mission, the following data shall be provided:

1. The number of samples of identical composition (for each composition).
2. The identity, weight and/or percentage of each component in each sample.
3. The dimensions and/or surface area of each sample.
4. The sample containment system (e.g. glass ampule, crucible).
5. The processing temperatures.
6. The processing times, including warm up duration, duration at nominal processing temperature, and cool down duration.
7. The fraction of the sample being heated at any one time and, for zonal melting experiments, the width and rate of movement of the heated zone.
8. The melting and boiling points of each component, if known.
9. The evaporation rate or vapor pressure of each component metal at maximum planned processing temperature and at maximum runaway temperature in case of failure of the temperature control system.
10. The measured weight lost by each sample during ground-based furnace processing (experimental data, if available).
11. The calculated weight lost by each sample during furnace processing, if available.
12. The atmosphere (inert gas, vacuum, ambient, etc.) in the furnace.
13. The maximum number of samples processed at one time.
14. A brief process description, including information about plans to open the furnace (e.g. for sample examination of change out) and procedures for doing so (i.e. purge prior to opening).

3.2.5 INFORMATION NEEDED SPECIFICALLY FOR BATTERIES AND CAPACITORS

HMST records shall only be submitted for previously unassessed battery chemistries and high-risk capacitors. Any battery chemistry submitted to EP5 that is not currently captured in generic battery HMST records included in Program-specific hazard reports must be assessed by JSC Toxicology. HMSTs must also be submitted for capacitors that are considered “high risk” (> 4000 mm or unknown size that are vented). Information for batteries and capacitors that require HMSTs will be captured in the hazard reports and must be submitted per Section 3.4. Battery requirements are specified in JSC-20793 Crew Space Vehicle Battery Safety Requirements and SSP 51721 ISS Safety Requirements Document. Most common battery chemistries are THL 2. A generic HMST entry will cover these chemistries and direct crew and ground to an appropriate clean-up response. The primary exception is lithium thionyl chloride Li-SOCl2, which are THL 4, and are currently not allowed to fly within the habitable volume of

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spacecraft. Capacitor requirements are specified in EP-18-113. Wet tantalum capacitors or aluminum electrolytic capacitors containing dimethylformamide or gamma-butyrolactone are considered THL 2. Aluminum electrolytic capacitors containing ethylene glycol are considered THL 1. Any other class of wet electrolytic capacitor will be considered THL 2 by default.

3.2.6 INFORMATION NEEDED SPECIFICALLY FOR BIOLOGICAL MATERIALS

HMST records for hardware containing biological materials shall include the BSLs assessed by the JSC BRB. The requirements for the type of information needed to facilitate the review of any biological materials are specified in JPR 1800.5.

3.3 HOW THE DATA SHALL BE FORMATTED AND SUBMITTED

All data shall be submitted in the eHMST tool available at: https://mycmc-apps-ext.jsc.nasa.gov/eHMST/

All applicable information fields to the particular type of chemicals in the payload (e.g., furnace or combustion experiments), shall be completed. Failure to provide complete information will delay any required hazard assessment. When completed, the eHMST record should be submitted for assessment via Tab 7 of the record.

3.4 WHEN DATA SHALL BE SUBMITTED

The timelines for submission of data are listed in Appendix C, Timeline Milestones for Submission of Data and Completion of HMST development and review. Earlier submissions are welcome and strongly recommended. Data submittal requirements and timeline milestones are consistent with safety review process requirements contained in SSP 30599. Safety reviews are conducted in phases from Phase 0 to Phase III. Preliminary HMSTs are strongly recommended for Phase 0 safety reviews and are required for Phase I safety reviews. Verification-1 (V-1) Verified HMSTs are required for Phase II safety reviews (see Appendix B for additional detail). Toxicity hazard assessments of proposed flight chemicals allow safety panels and EIPs to identify, understand, and plan for potential hazards early in the design life cycle of the hardware. It is for this reason that early data submittals of information on proposed flight chemicals are strongly encouraged and expected.

Toxicity hazard assessments are officially communicated to the EIP primarily via HMST records but may also be provided as Toxicity Hazard Assessment Memoranda. It is the EIP's responsibility to provide the official hazardous materials assessment and any subsequent updates to the Safety Panel of record. HMST records proceed through three steps (see Appendix B):

1. Preliminary - Preliminary HMST records are highly recommended for Phase 0 technical interchange meetings with Safety and are required for Phase I safety reviews,

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2. V-1 Verified - V-1 Verified HMST records shall be submitted to support of Phase II safety reviews, and
3. V-2 Verified - V-2 Verified HMST records shall be submitted to confirm that the contents reflect the "as loaded" condition of the hardware and are used to close out the related hazard reports and/or safety verification tracking log.

The EIP must take into account the various phased safety review dates and SDP deliverable deadlines and submit requests for toxicity assessments in advance of those deadlines. JSC Toxicology strives to complete all assessments in a timely manner but requests a minimum of 10 business days. Highly complex hardware or hardware with a large number of chemicals may require additional time for review and assessment. While other assessments are performed concurrently, refer to documents identified in Section 1.4 for additional details other SME timelines. Failure to submit supporting HMST records appropriate for the particular phased safety review may result in design impacts and/or delay of completion of the phased safety review.

3.5 HOW PROPRIETARY DATA WILL BE HANDLED

All data provided to JSC Toxicology are handled with discretion, and dissemination of proprietary data will be limited to NASA and contractor personnel who have a valid need to know. Due to extra measures required to handle proprietary data, JSC Toxicology requests that the EIP limit the designation to the specific data that should be considered proprietary (e.g., the identity, but not the concentration of each constituent). Proprietary data may be submitted by request in the eHMST tool. Although generally not required, please note that if non-disclosure agreements are requested, the total time required for assessments may increase significantly. In this case it is especially important for the EIP to submit data well in advance of the 10 business day timeline noted above to ensure that the assessments are completed in advance of safety reviews.

4.0 PREVIOUSLY ASSESSED MATERIALS

4.1 REFLIGHT AND SERIES ITEMS

Reflight items have flown before under an identical part and number (using the same part number and serial number), and the materials in the hardware are identical (unmodified) to those previously flown. Series items include updates to the hardware quantity or serial number only and contain materials that are identical to those previously flown. Non-flight-specific (NFS) records may be generated for reflight or series items in well-established, mature hardware/systems (> 3 years) that fly routinely (> 3x/year). These records do not require an association with a flight manifest and may be referenced in reflight Safety documentation. Records generated in the eHMST tool can be cloned for future flights to help expedite submittal of reflight or series items that are not eligible for NSF records. Please note prior assessments

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(by flight and eHMST record number) in the Previous Mission Information field on Tab 1 of the eHMST record. If/when items are modified a new record must be submitted per Section 4.2 below. Modifications include but are not limited to changes in amounts, concentrations, or microbial strains, in addition to actual ingredients.

NOTE: The use of NSF records is generally only applicable to ISS since the flight cadence of Artemis is expected to be less than 3x/year. The development of flight-specific HMSTs for series/reflight hardware via cloning of baseline records is acceptable.

4.2 MODIFIED ITEMS

If the hardware is similar to that flown previously but with different part numbers or the materials have changed significantly (such as material identity, concentration, or amount), the EIP shall follow the process described in this document in full. Note that other groups may have additional requirements for modified items.

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APPENDIX A. ACRONYMS AND ABBREVIATIONS

BRB	BioSafety Review Board
BRES	BioMedical Research and Environmental Sciences Division
BSL	BioSafety Level
CFE	Customer Furnished Equipment
ECLSS	Environmental Control and Life Support System
eHMST	Electronic Hazardous Materials Summary Table
eSAT	Electronic Stowage Assessment Tool
EIP	End Item Provider
ES4	JSC Materials and Processes Branch
ESERP	Exploration Systems Directorate Safety and Engineering Review Panel
FHL	Flammability Hazard Level
GFE	Government Furnished Equipment
HHP	Human Health & Performance Directorate
HMST	Hazardous Materials Summary Table
HRL	Hazard Response Level
ISRP	ISS Safety Review Panel
ISS	International Space Station
JSC	Johnson Space Center
JSERP	Joint Safety and Engineering Review Panel
MIDAS	NASA Mission Integration Database Application System
MPCV	Multi- Purpose Crew Vehicle
MSERP	Multipurpose Crewed Vehicle Safety & Engineering Review Panel
NASA	National Aeronautics and Space Administration
NFS	Non Flight Specific
Ops	Operations
OSHA	Occupational Safety and Health Administration
PDMS	Polydimethylsiloxane

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pH	potential of hydrogen
POC	Point of Contact
RCP	JSC Radiation Constraint Panel
RPWG	Radioactive Payloads Working Group
SA	Human Health and Performance (HHP) Directorate
SD2	JSC Space Radiation Analysis Group
SDP	Safety Data Package
SDS	Safety Data Sheet
SME	Subject Matter Expert
SRAG	Space Radiation Analysis Group
STRB	Safety Technical Review Board
TBD	To Be Determined
THL	Toxicity Hazard Level
U.S.	United States
V-1	Verification-1
V-2	Verification-2

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APPENDIX B. THE HAZARDOUS MATERIALS SUMMARY TABLE (HMST) DEVELOPMENT AND VERIFICATION PROCESS

Potential toxicological hazards associated with system/payload chemicals are communicated through the issuance of HMST records. These assessments, which, according to SSP 30599, are required components of safety data packages (SDP), can only be issued by JSC Toxicology. The official toxicological assessments and THL(s) allow safety panels to understand and assess the relative risk associated with chemicals proposed for use on crewed vehicles.

HMST records utilized for Phase 0, I, and II safety reviews are generally launch-vehicle independent. However, as a payload/hardware is officially assigned a launch vehicle/mission, the HMST records are transitioned to become mission specific except in cases where NFS records have been developed (see Section 4.1). This means that a new set of HMST records are created for each launch of a crewed space vehicle or launch of a pressurized cargo vehicle that will dock to or be berthed with a crewed vehicle. The mission-specific HMST records are composed of individual database records of payloads, system components, equipment, supplies, medications, etc. that contain chemical and biological materials planned to be launched on a particular vehicle.

HMST records are developed and verified in a three-step process. A “Preliminary” step or phase for initial information gathering and maturation, and two “Verification” steps for confirming completeness and accuracy of data on each HMST record and for confirmation of items loaded onto a launch vehicle. This process is summarized in Figure 1, The Hazardous Materials Summary Table Development and Verification Process.

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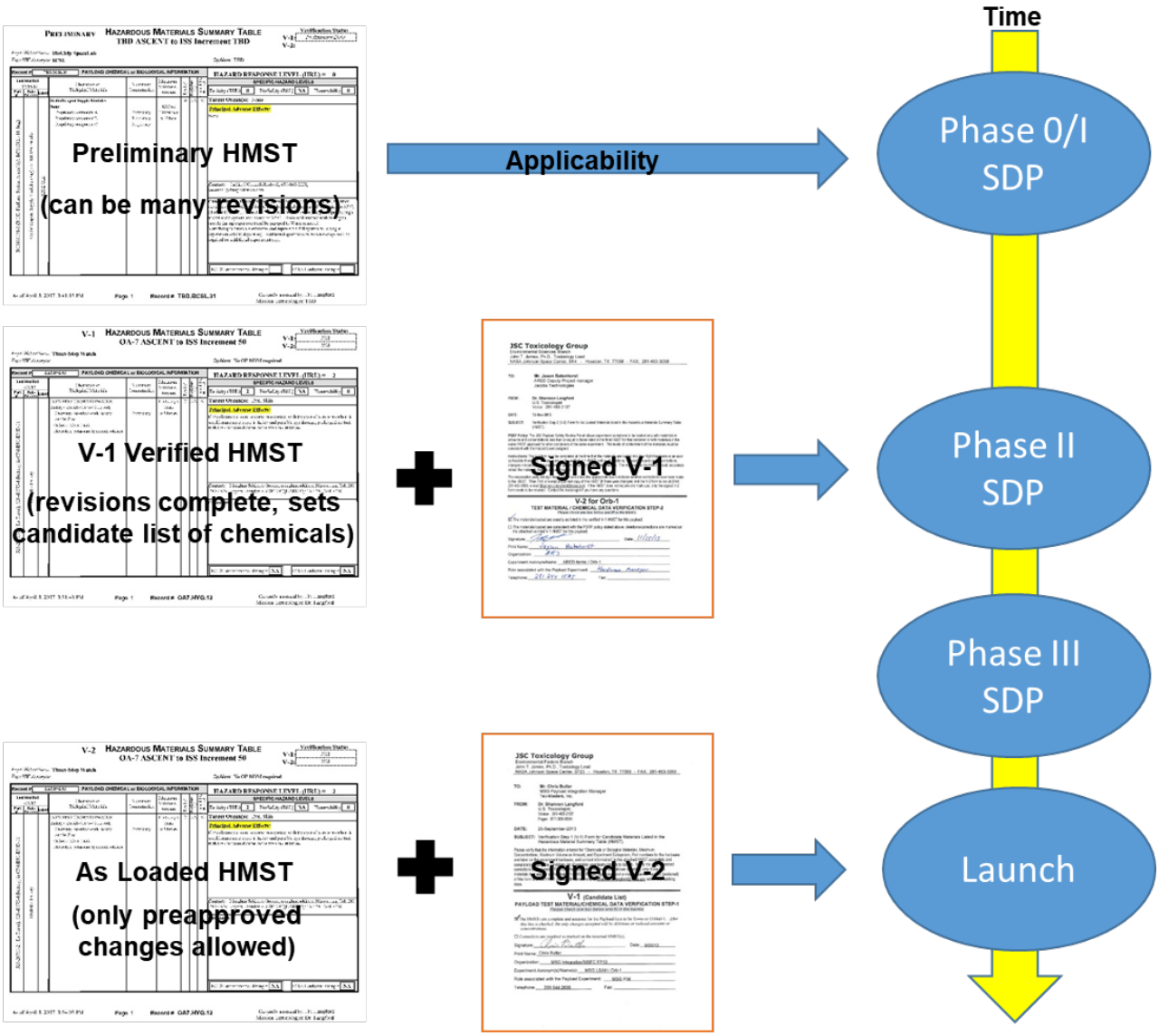

FIGURE 1 - THE HAZARDOUS MATERIALS SUMMARY TABLE DEVELOPMENT AND VERIFICATION PROCESS

The Preliminary HMST

Development of HMST records commences by development of draft records based on the initial EIP data submittal input. Once records are submitted via eHMST, and receive all required SME assessments, they will be considered "Preliminary" HMST record(s). Preliminary HMST records may be used in early phase SDP submittals (Phase 0 and I). It is understood that

information about a payload may change in the months to years leading up to it being launched. For this reason, HMST records will usually remain labeled as Preliminary until the time specified in the timeline section below.

Verification Process

Safety panels and JSC Toxicology use a two-step verification process to assure that accurate and complete information about chemicals proposed for launch is gathered and assessed (Verification-1 step) and then only the items assessed and approved are actually loaded onto a launch vehicle (Verification-2 step).

The Verification-1 (V-1) verified HMST

The V-1 process assures that JSC Toxicology has a complete and accurate list of all candidate materials that are being considered for flight in a particular end item (a "final candidate" list). The EIP can promote a record to V-1 verification status via the action buttons in eHMST at the bottom of Tab 7 of each record once all assessments (toxicity, flammability, biosafety, ECLSS, etc.) are complete. As described in the Policy for Changes to the HMST noted on the V-1 form, the only changes allowed to V-1 HMST records are deletions or reduced amounts or concentrations of the assessed chemicals. V-1-Verified HMST records are required for Phase II safety reviews.

Policy on Changes to the HMST

After the V-1 document has been verified as complete and accurate within eHMST, additions of new materials or increases in concentrations or quantities per container shall require the approval of the Chairman of the applicable Safety Review Panel. Deletions or reductions in quantities per container or concentrations and changes in location are permitted after V-1 completion.

The Verification-2 (V-2) verified HMST

The V-2 process assures that the Lead Mission Toxicologist has a complete and accurate list of the materials selected by the EIP from the V-1 candidate list that were actually loaded into the flight hardware. The term "loaded" is broadly used here to denote specific milestones of hardware and/or payload delivery in the hours to weeks prior to launch. The V-2 step shall be completed by the EIP POC as soon as feasible after the materials are physically placed into the hardware and/or the hardware is handed over to cargo processors. The time at which this occurs may vary widely for nominal versus late load items. For "late load" items, V-2 verification step shall be completed no later than 24 hours after launch.

The EIP can promote a record to V-2 verification status via the action buttons at the bottom of Tab 7 of each record once a part number has been provided, a manifest association has been

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made via Tab 5 of the record, and the chemical and/or biological components have been physically placed into the hardware.

The V-2 process for launch slips, launch scrubs, or remanifesting:

After a payload has been loaded and verified (V-2 completed), if a launch delay requires that the chemicals in the payload be refurbished, the V-2 process shall be repeated if a different subset of approved candidate chemicals are selected from the V-1-verified HMST for subsequent loading. Only materials that were included as candidates in the original V-1-verified HMST records may be loaded for the flight.

> IF ALL MANIFESTED ITEMS IN AN EHMST RECORD MOVE TO A DIFFERENT FLIGHT, THEY SHOULD REMAIN APPROPRIATELY ASSIGNED AS THE MANIFEST CHANGES. IF ITEMS ARE SPLIT MANIFESTED, THE EIP MUST RETURN THE RECORD TO V-1 VERIFICATION STATUS VIA THE ACTION BUTTONS ON TAB 7, UPDATE THE MANIFEST ASSOCIATION ON TAB 5 AND THEN RETURN TO V-2 VERIFICATION STATUS.

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APPENDIX C. TIMELINE MILESTONES FOR SUBMISSION OF DATA AND COMPLETION OF HAZARDOUS MATERIALS SUMMARY TABLE (HMST) DEVELOPMENT AND REVIEW

Adherence to the following timelines for submission of data is important for JSC Toxicology to be able to provide hazard assessments before safety reviews and to support EIP and JSC Toxicology deliverables associated with each mission.

At hardware/payload inception:

Early submission of a preliminary list of all candidate materials, as well as preliminary support data (process temperatures, durations, SDS, etc.) will enable the Toxicologist to make an early toxicological assessment and allow ECLSS engineering to assess all potential hardware and environmental compatibility impacts in a timely manner. This will help the EIP representative to ensure that planned containment and other safeguards are adequate before the final design or construction of the flight article. Preliminary HMST records are encouraged for Phase 0 Safety Reviews. If the EIP plans/desires to include HMST records in their Phase 0 SDP, data shall be submitted with adequate time for review and preliminary HMST development.

For payloads with large numbers of different materials, it is especially important that lists of chemical or biological materials be submitted as early as possible. If a long list (>40 materials) is submitted at the designated time for a safety review (see below), it may not be possible to assess all of these chemicals in time to support the phased review.

Prior to Safety Review

Preliminary HMST records are required for the Phase I Safety Review, and V-1 verified records are required for the Phase II Safety Review. To ensure that all required assessments (toxicity, flammability, biosafety, and ECLS compatibility) can occur, it is recommended that EIPs submit data at least 35 business days ahead of their safety data submittal deadlines. More time should be allotted by the EIP if preliminary records were not developed for earlier safety reviews and/or the request includes lengthy list(s) of materials (e.g. protein crystallography experiments).

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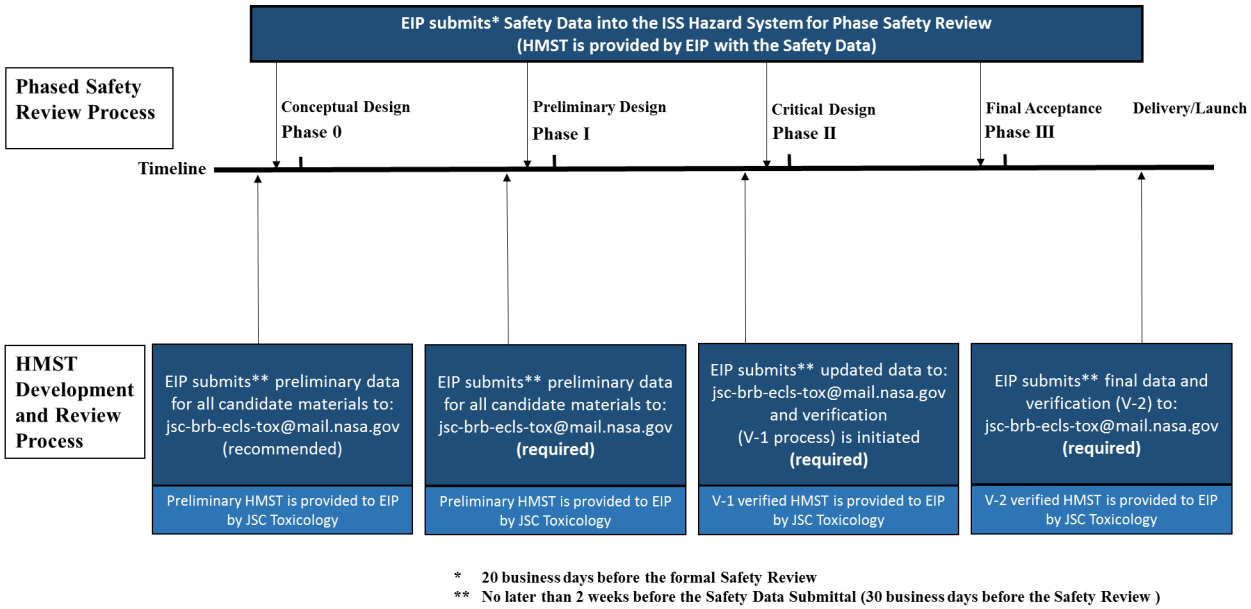

FIGURE 2 - OVERVIEW OF TIMELINE FOR HMST SUBMISSION IN SUPPORT OF SAFETY REVIEW PROCESS

Process for hardware/payloads returning in the habitable volume of a space vehicle:

HMSTs are initially developed and linked to flight of record for launch. However, they consider all mission phases (launch, stowage, operations, and return). Therefore, these records should account for hardware/payloads returning on crewed space vehicles and that will be located inside the habitable volume of that vehicle. Submission of the 'launch' HMST should be adequate for safety assessment and approval by the ISRP/IP visiting vehicle safety authority (reference section 8 of SSP 30599, Rev. F) in most cases. If the original assessment for an item planned for return on a crewed space vehicle did not include an assessment of this case, JSC Toxicology will support development of HMST records for return safety assessment/approval by the ISRP/IP visiting vehicle safety authority.