



Conducting Airborne Electronic Hardware Reviews

Job Aid

**Aircraft Certification Service
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ACRONYMS

ACO	Aircraft Certification Office
ASE	Aviation Safety Engineer
ASE-HW	Aviation Safety Engineer-Hardware
ASE-SW	Aviation Safety Engineer-Software
ASI	Aviation Safety Inspector
ASTC	Amended Supplemental Type Certificate
ATC	Amended Type Certificate
C/F/O	Compliances/Findings/Observations
CEH	Complex Electronic Hardware
CM	Configuration Management
COTS	Commercial Off-The-Shelf
CRI	Certification Review Item
CSTA	Chief Scientific and Technical Advisor
DAR	Designated Airworthiness Representative
DER	Designated Engineering Representative
DMIR	Designated Manufacturing Inspection Representative
ENG	Engineering
FAA	Federal Aviation Administration
FFPA	Functional Failure Path Analysis
HAS	Hardware Accomplishment Summary
HC1	Hardware Control Category 1
HC2	Hardware Control Category 2
HCMP	Hardware Configuration Management Plan
HDL	Hardware Description Language
HDP	Hardware Design Plan
HPAP	Hardware Process Assurance Plan
HQ	Headquarters
HVP	Hardware Validation/Verification Plan
HW	Hardware
I/O	Input/Output
NA	Not Applicable
PA	Process Assurance
PA/CM	Process Assurance/Configuration Management
PDH	Previously Developed Hardware
PHAC	Plan for Hardware Aspects of Certification
POC	Point of Contact
PI	Principal Inspector
RTCA	RTCA, Inc. (formerly Radio Technical Commission for Aeronautics)
RTL	Register Transfer Language (commercial brand name)
SEH	Simple Electronic Hardware
SOI	Stage of Involvement
SOIs	Stages of Involvement
SSA	System Safety Assessment
STC	Supplemental Type Certificate

TC	Type Certificate
TS	Technical Specialist
TSOA	Technical Standard Order Authorization

PART 1 – OVERVIEW OF THE AIRBORNE ELECTRONIC HARDWARE REVIEW

Purpose

This Job Aid assists certification authorities, designees (including organization delegations), and applicants in performing airborne electronic hardware reviews (which will be referred to as “hardware reviews” for the remainder of this document). The purpose of the hardware review is to assess whether or not the airborne electronic hardware complies with airworthiness requirements and the proposed means of compliance (i.e., RTCA/DO-254).

This Job Aid should be used as a reference tool during the review process. It is **not** intended to be used as a checklist and is **not** all inclusive of all possible situations that need to be reviewed. Nor is the Job Aid intended to replace DO-254. Rather, it should be used in conjunction with DO-254. Likewise, this Job Aid may include questions that are not appropriate for the specific project being evaluated. Reviewers should keep in mind that each project has some unique characteristics and should use the Job Aid as it best fits the specific situation. This Job Aid only addresses the hardware review prior to certification/authorization for the following processes: Type Certificate (TC), Supplemental Type Certificate (STC), Amended Type Certificate (ATC), Amended STC (ASTC) or Technical Standard Order Authorization (TSOA).

Additionally, this Job Aid includes review questions where the connection between these questions and the referenced DO-254 objectives may not be immediately obvious. However, these types of questions may be instrumental in helping a reviewer determine compliance for the hardware in the context of the system in which that hardware resides.

Examples of issues that these questions may address include:

- Concerns regarding the use of the hardware as part of the overall system, e.g., whether the system still meets the requirements of the system safety assessment due to derived hardware requirements.
- Compliance of the hardware and the processes used to develop and verify that hardware to FAA policy, issue papers, and non-U.S. certification authorities’ position papers.
- Integration issues, such as board level integration and hardware/software integration concerns.

For example, integration testing is a primary concern when that level of

testing is used to show compliance to DO-254 for individual hardware components. Hardware/software integration testing is important, as many of the individual complex hardware components may have been developed to perform functions traditionally performed in software run on the main system processor. Examples of this include complex input/output functions, monitoring and safety protections, such as a memory management unit. Thus, the hardware being reviewed may be very tightly coupled to the software design. Additionally, the reviewer will need to be aware of any applicable policy when reviewing any hardware project, including that from non-U.S. certification authorities, such as EASA. The FAA may be finding compliance for a non-U.S. certification authority, and therefore will need to be aware of the policy and position papers that apply.

For the purposes of this Job Aid, **Compliance**, **Finding**, and **Observation** are defined as follows:

- ⊞ A **Compliance** is the satisfaction of a DO-254 objective (and the related guidance contained in the text of DO-254);
- ⊞ A **Finding** is identification of non-compliance to a DO-254 objective (and the related guidance contained in the text of DO-254);
- ⊞ An **Observation** is identification of a potential process improvement.

The Job Aid will assist the hardware reviewer to do the following:

- ⊞ Perform tasks associated with conducting a hardware review.
- ⊞ Document Compliances, Findings and Observations.
- ⊞ Link review Compliances, Findings and Observations to DO-254 objectives.

Job Aid Layout

This Job Aid addresses:

- ❖ Tasks to be performed before, during, and after a hardware review (Part 2).
- ❖ Activities and questions to be considered during a review (Part 3).
- ❖ An approach to the Findings and Observations to DO-254 objectives (Part 4).

Stakeholders in the Hardware Review Process

Below is a high-level description of the role of the key players/stakeholders in the hardware review process.

Table 1. Stakeholders in the Hardware Review Process

Stakeholders	Primary Role in Hardware Review
Aviation Safety Engineer Hardware (ASE-HW)	<ul style="list-style-type: none"> • Responsible for the hardware approval on the project being reviewed. • Serves as the review team leader and is responsible for coordination, scheduling and other review activities. • Reviews the technical aspects of the hardware design process.
Aviation Safety Engineer (ASE)	<ul style="list-style-type: none"> • Works in propulsion, avionics/electrical systems, or mechanical systems with responsibility for approval of the overall system whose hardware is being reviewed. • May not have hardware expertise, but is familiar with the system requirements, safety aspects, and system performance expectations. • May accompany the hardware review team to provide a tie to the systems aspects of the project and to review requirements. • Needs to be informed of status on hardware, software, and safety issues.
Aviation Safety Engineer Software (ASE-SW)	<ul style="list-style-type: none"> • Responsible for, or involved in, the software approval on the project being reviewed. • Understands the issues regarding hardware to software integration. • May accompany the hardware review team to provide a tie to the software aspects of the project and to review requirements.
Aviation Safety Inspector (ASI)	<ul style="list-style-type: none"> • Principal inspector for the applicant being evaluated. • Performs conformity inspections on the hardware.

Flight Test Engineer/Pilot	<ul style="list-style-type: none"> • Evaluates the aircraft or the system installed on the aircraft by performing system demonstrations, simulations, and aircraft ground and flight tests. • Evaluates the system performance on the aircraft and identifies any safety, operational, or performance concerns. • Needs to be informed of status on hardware issues.
Chief Scientific & Technical Advisor (CSTA)	<ul style="list-style-type: none"> • Serves as a technical consultant on novel or unique projects that require expert review and input, as needed.
Technical Specialist (TS)	<ul style="list-style-type: none"> • Serves as a technical expert and a resource for the ASE-HW and ASI-HW during the hardware review process. • May serve as a link between the ASE-HW and the CSTA.
Project Manager	<ul style="list-style-type: none"> • Responsible for schedule and oversight of the overall project.
Directorate Hardware Personnel	<ul style="list-style-type: none"> • Involved in any situations that could affect Directorate policy, issue papers or special conditions for novel technology. • Provides technical expertise, when needed.
Headquarters (HQ) Hardware Personnel	<ul style="list-style-type: none"> • Involved in projects that require changes or additions to national hardware policy. • Serve as technical experts during the hardware review, as needed.
Designated Engineering Representative (DER)	<ul style="list-style-type: none"> • Works on behalf of the FAA to review hardware projects. • Acts as part of the review team. • Often performs review prior to the FAA review to make preliminary compliance findings and to resolve any issues.
Designated Manufacturing Inspection Representative (DMIR), Designated Airworthiness Representative (DARs)	<ul style="list-style-type: none"> • Works on behalf of the FAA to perform hardware conformities.

<p>Applicant</p>	<ul style="list-style-type: none"> • Applies for Type Certificate, Supplemental Type Certificate, Amended Type Certificate, Amended Supplemental Type Certificate or Technical Standard Order Authorization. • Responsible for the hardware compliance. May or may not be the hardware developer. • Oversees hardware developer, if applicable. • Attends on-site hardware review. Note: If the applicant is not the hardware developer, the applicant’s hardware Process Assurance (PA) and hardware Configuration Management (CM) personnel, systems engineer, and other team members should be present at on-site reviews.
<p>Hardware Developer</p>	<ul style="list-style-type: none"> • Includes applicant and/or developer of the hardware to be installed on an aircraft. (May be supplier to applicant.) • Members of hardware developer team include: hardware program manager, hardware engineers, hardware designers, hardware PA personnel, hardware CM personnel, etc.

<p>Review Types</p>	<p>There are two types of reviews used to determine if an applicant’s hardware design complies with DO-254 objectives: (1) on-site review and (2) desk review. Applicants or developers may also perform self-assessment reviews (for example, through their hardware PA organization). The table below provides a brief description of each type of review, when each type is appropriate, and the advantages/disadvantages of each. This Job Aid addresses both the on-site and desk reviews.</p>
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Table 2. On-Site/Desk Review Summary

Type/Description	When Appropriate	Advantages/ Disadvantages
<p>On-Site Review:</p> <ul style="list-style-type: none"> • Review appropriate phases of the hardware design process. • Conducted by team at the hardware developer's facility. (Note: Applicant's designees should be present). 	<ul style="list-style-type: none"> • Highly critical systems. • New system being developed. • First-time applicants or first-time users of DO-254. • Applicant inexperienced in developing and/or overseeing hardware. • Applicants with history of poor design processes. • New/unique hardware, design, verification and/or manufacturing concepts. • When a system demonstrates multiple problems during systems and flight-testing. • Major changes in the environment (e.g., personnel, tools, methods). • At request of designee. • FAA oversight of a designee is needed. 	<p>Advantages:</p> <ul style="list-style-type: none"> • Access to development personnel. • More in-depth review. • Higher confidence in safety aspects. • Complete access to data. • Helps perform designee performance evaluation. <p>Disadvantages:</p> <ul style="list-style-type: none"> • Budget and time considerations.
<p>Desk Review:</p> <ul style="list-style-type: none"> • Review appropriate life cycle data. • Conducted by team at FAA or applicant's facility. • Little or no involvement by the hardware developer. 	<ul style="list-style-type: none"> • Changes to current FAA-approved hardware. • Less critical systems. • Experienced companies with a good history. 	<p>Advantages:</p> <ul style="list-style-type: none"> • Not as disruptive to the hardware developer's schedule. • Budget and time considerations <p>Disadvantages:</p> <ul style="list-style-type: none"> • Many companies do not allow data to be viewed without their presence. • Cannot ask direct questions of hardware developers. • May require large shipment of data. • May postpone closure of questions and issues due to remote communication.

The use of designees for hardware reviews is encouraged, when appropriate. Table 3 outlines when the delegation of a review is appropriate and some of the advantages/disadvantages of delegation.

Table 3. Delegation of Hardware Reviews

When Appropriate	Advantages/Disadvantages
<ul style="list-style-type: none"> • Demonstrated good proven “track record” with proper authorization. • For all systems without unique hardware characteristics. • When there are no issues that have policy implications (Directorate or Headquarters). 	<p>Advantages:</p> <ul style="list-style-type: none"> • May be familiar with applicant’s processes and data organization. • Can spend more time on-site and can monitor the processes throughout the design. • May be able to support schedule better than FAA employees. <p>Disadvantages:</p> <ul style="list-style-type: none"> • May have company bias. • May be pressured to “cut corners” when schedules are slipping.

The hardware review may be used for the evaluation and subsequent approval of hardware data within the TC, ATC, STC, ASTC and TSO processes.

The purpose of the hardware review is to assess whether or not the airborne electronic hardware complies with airworthiness requirements and the proposed means of compliance (assumed to be RTCA/DO-254). To assess compliance, there are typically four Stages of FAA Involvement throughout the hardware life cycle of a project. The four Stages of Involvement (SOIs) are listed below and overviewed in Table 4:

- (1) Planning review;
- (2) Design review;
- (3) Validation and Verification review
- (4) Final review.

For each Stage of Involvement (SOI) the following information is provided: a brief description of the SOI, required data, related DO-254 objectives used as evaluation criteria, and related Job Aid Sections.

Reviews may be combined or delegated to an authorized designee, as the project requires. If the FAA elects not to perform four reviews, it is strongly encouraged that designees perform on-site reviews and/or the applicant conducts internal compliance reviews using the approach outlined in this Job Aid.

For some projects, more than four reviews may be warranted. For example, more than four reviews may be appropriate for a large project with many sub-systems or a project with many problems.

Table 4. Overview of Stages of Involvement

Stage of Involvement	Description	Data Required	Related DO-254 Objectives reference	Related Job Aid Section
1	<p>Planning review</p> <ul style="list-style-type: none"> – Assure plans meet DO-254 objectives. – Assure that the processes described in the applicant's plans meet the objectives of DO-254. – Obtain agreement between FAA and applicant on the plans. 	<ul style="list-style-type: none"> • Plan for Hardware Aspects of Certification (PHAC) • Hardware Validation/ Verification Plan (HVP) • Hardware Design Plan (HDP) • Hardware Configuration Management Plan (HCMP) • Hardware Process Assurance Plan (HPAP) • Hardware Design Standards • Safety assessment 	<p>4.1(1) 4.1(2) 4.1(3) 4.1(4)</p>	<p>Section 3.1 - Activities for SOI #1</p>
2	<p>Design review</p> <ul style="list-style-type: none"> – Assess implementation of plans and standards in the hardware life cycle data. – Assess and agree to plan changes. – Assure life cycle data meets DO-254 objectives. 	<ul style="list-style-type: none"> • Hardware Design Standards • Hardware Requirements • Hardware Design Description (Note: Hardware Design Description refers to data described in DO-254, section 10.3.2 and subsections, particularly section 10.3.2.1.) • Detailed Design Data (e.g., HDL, schematics) • Problem Reports • Hardware Configuration Management Records • Hardware Process Assurance Records 	<p>5.1.1(1) 5.1.1(2) 5.1.1(3) 5.2.1(1) 5.2.1(2) 5.2.1(3) 5.3.1(1) 5.3.1(2) 5.3.1(3) 5.4.1(1) 5.4.1(2) 5.4.1(3) 5.4.1(4) 5.5.1(1) 5.5.1(2) 5.5.1(3) 5.5.1(4) 7.1(1) 7.1(2) 7.1(3) 8.1(1) 8.1(2)</p>	<p>Section 3.2 - Activities for SOI #2</p>

Stage of Involvement	Description	Data Required	Related DO-254 Objectives reference	Related Job Aid Section
			8.1(3)	
3	<p>Validation and Verification review</p> <ul style="list-style-type: none"> - Assess implementation of verification and test plans and procedures. - Check completion of all associated CM and Process Assurance tasks. - Ensure hardware requirements are verified. - Ensure validation and verification activity satisfied requirements in DO-254. 	<ul style="list-style-type: none"> • Hardware Requirements • Hardware Design Description • Detailed Design Data (e.g., HDL, schematics) • Hardware Verification Cases and Procedures (Note: Hardware Verification Cases and Procedures refer to data described in Do-254, sections 10.4.2 and 10.4.4.) • Hardware Verification Results (Note: Hardware Verification Results refer to data described in Do-254, sections 10.4.3 and 10.4.5.) • Problem Reports • Hardware Configuration Records • Hardware Process Assurance Records • Hardware Conformity Records 	<p>6.1.1(1) 6.1.1(2) 6.1.1(3) 6.2.1(1) 6.2.1(2) 6.2.1(3) 6.2.1(4) 7.1(1) 7.1(2) 7.1(3) 8.1(1) 8.1(2) 8.1(3)</p>	Section 3.3 - Activities for SOI #3
4	<p>Final review</p> <ul style="list-style-type: none"> - Assures final hardware product meets DO-254 objectives and is ready for certification. - Address any open items. 	<ul style="list-style-type: none"> • Hardware Life Cycle Environment Configuration documentation • Hardware Configuration documentation • Problem Reports • Hardware Accomplishment Summary (HAS) 	All	Section 3.4 - Activities for SOI #4

Determining Level of Involvement

As early as possible in the project, the FAA should estimate the required level of involvement. The process for determining and documenting the FAA level of involvement is described in Chapter 3 of Order 8110.CEH*. Early in the project, the FAA should evaluate such things as: the applicant's experience, the history of the applicant, the quantity and experience of designee support, the novelty/ uniqueness of the project, and the project criticality. Based on this early evaluation, the FAA will determine if the level of involvement is high, medium, or low. The level of FAA involvement will dictate the number of hardware reviews, the stages of involvement, and the nature of the review (i.e., desk or on-site).

For example, for a highly critical system being developed by a company who has never used DO-254, the level of FAA involvement would likely be high and on-site hardware reviews would be performed at all Stages of Involvement.

The FAA's involvement should be determined and documented as early as possible in the project.

*Order 8110.CEH will cover aspects of both Complex and Simple Custom Micro-Coded Devices, also referred to as CEH (Complex Electronic Hardware devices) and SEH (Simple Electronic Hardware devices). This Order has not been published at the time of initial publication of this Job Aid, and therefore cannot be referred to by a specific Order number or title.

The Review Team

It is recommended that reviews be performed using a team of two to four people. A team can typically perform a higher quality review than an individual and can reduce the amount of time required to perform the review. The review team will typically divide responsibilities. Depending on the size of the team, there should be at least one team member that will focus on design and/or validation/verification data, and another team member that will focus on process assurance and configuration management processes. In addition to the hardware engineers, there may be one or more non-hardware engineers (e.g., software engineers, systems specialists) as part of the team to oversee the systems, safety, and application aspects of the project. Throughout this Job Aid, the areas of responsibility will be highlighted. Additional team members may be a Chief Scientific and Technical Advisor, Technical Specialist, Directorate personnel, Headquarters personnel, or international certification authorities, as required or as available.

PART 2 – HARDWARE REVIEW TASKS**Overview of Common Tasks**

Regardless of the Stage(s) of Involvement for the hardware review, the following four tasks will be done for each review:

- (1) Preparing for the review;
- (2) Performing the review (referencing the appropriate Job Aid tables and documenting the review findings and observations);
- (3) Preparing and delivering an exit briefing of the review; and
- (4) Conducting follow-up activities (e.g., prepare a report, assess if another review is required or if final compliance has been demonstrated).

The following pages give a detailed description of the four tasks performed by the review team in conducting a hardware review. The person(s) responsible for each task is listed next to the task. The “team leader” is the ASE-HW or designee responsible for leading the review. The “team” is typically comprised of ASE-HWs, designees, and others, as needed.

Once the SOI has been established, refer to the appropriate Activities/Questions for Stage of Involvement in Part 3. The Part 3 tables provide guidance as to what kinds of questions to ask to ensure that the DO-254 objectives are met. If there is more than one SOI combined in a review, more than one set of tables will be referenced (e.g., if the reviews combine SOI #1 and SOI #2, tables for both SOIs would be used).

The table in Part 4 of this Job Aid shows a method of capturing the results of a hardware review and allows the review team to record a Compliance, Finding or Observation for each DO-254 objective. There are several things to keep in mind when answering the questions of the tables in Part 3 and filling out the table in Part 4. The review team must be very clear and meticulous when documenting a Finding of non-compliance to a DO-254 objective. The Finding must be able to be documented in such a way that **clearly identifies which DO-254 objective the non-compliance is against and why the item is non-compliant**. This will assist the hardware developer and/or applicant in understanding exactly what needs to be corrected in order to bring the item into compliance.

An answer of “no” to any particular question listed in a Part 3 table does not automatically mean that an item is non-compliant. For example, a question such as “Is each test case and procedure appropriately commented?” should not, in most cases, result in a Finding of non-compliance to DO-254 objectives. At most, a “No” answer to that question should be an Observation. Each question in the Part 3 tables, and the answer to each question, must be assessed in the overall context and scope of the review before deciding upon the classification of the answer. Because compliance to DO-254 is one acceptable means of showing compliance to the regulations, a Finding of non-compliance to DO-254, by extension, means non-compliance to those CFR paragraphs. Care must be taken to avoid unnecessary disagreements between the hardware review team and the company being reviewed about Findings of non-compliance.

Whatever documentation method is chosen, remember certification is determined based on evidence of compliance. Be clear that you show evidence of correct implementation of the guidance and not only evidence of non-compliances that were fixed. Documentation should be thorough enough such that compliance activities can be repeated, if necessary, in support of the result.

The Tasks and Activities/Questions outlined emphasize the on-site hardware review. However, the same types of activities are appropriate for a desk review. The desk review would require a different type of notification letter and access to the applicant’s personnel might be limited to telephone calls. But the remainder of the activities is very similar. Places where the desk review differs from the on-site review are highlighted at the end of each task.

TASK 1: Preparing for the Hardware Review

The purpose of this task is to prepare for the hardware review by assembling the review team, notifying the applicant of the review, coordinating delivery of materials, and preparing all team members for the hardware review.

STEP 1: COORDINATE WITH THE CERTIFICATION TEAM (TEAM LEADER)

- 1.1 Inform the project manager of the plans to conduct a hardware review and discuss all concerns (e.g., issue papers, project impact).
- 1.2 Coordinate with and obtain necessary information from ASEs and Flight Test certification team members. **Note:** It may be beneficial to have systems and software ASEs on the hardware review team.
- 1.3 Inform Principal Inspector of intentions and coordinate any concerns.
- 1.4 If the hardware review is to be performed at a hardware developer's facility located in another cognizant Aircraft Certification Office's (ACO) area of responsibility, contact the appropriate ACO engineer for coordination. The other ACO engineer(s) may desire to be part of the review team in order to carry out routine oversight roles.
- 1.5 Address any non-US certification concerns with the FAA certification team and the international certification team, if appropriate.

STEP 2: ORGANIZE THE REVIEW TEAM (TEAM LEADER)

- 2.1 Determine the members of the review team, based on project needs.
 - √ Team should consist of at least one engineering team member (ENG) and one process assurance/configuration management (PA/CM) team member.
 - √ Designees assigned to the project should be involved as part of the review team.
 - √ Aviation Safety Engineer (ASE), Principal Inspector (PI), Chief Scientific and Technical Advisor (CSTA), Technical Specialist (TS), Directorate software personnel, or Headquarters (HQ) software personnel may be part of the team, as needed.
- 2.2 Coordinate a date for the review with the applicant and team members.

STEP 3: SEND A NOTIFICATION LETTER TO THE APPLICANT AT LEAST ONE MONTH PRIOR TO THE REVIEW (TEAM LEADER)

- 3.1 The notification letter should inform the applicant of the: (1) purpose of the review; (2) proposed agenda; (3) data to be reviewed during the review; and (4) data to be sent to the review team members prior to the review.
- v If the review combines Stages of Involvement, the contents of the agendas may be combined.

STEP 4: COORDINATE WITH REVIEW TEAM MEMBERS (TEAM LEADER)

- 4.1 Assure that all review team members have copies of the Plan for Hardware Aspects of Certification (PHAC), Hardware Design Plan (HDP), Hardware Validation/Verification Plan (HVP), Hardware Configuration Management Plan (HCMP), Hardware Process Assurance Plan (HPAP), and any other appropriate documentation at least two weeks prior to the review.

Note: While these may not be the final copies of the plans since they may change throughout the design process, the documents should be under configuration control.

- 4.2 Assign responsibilities to team members:

- v All team members should review all plans and prepare a list of questions/concerns on those plans to clarify with the applicant at the review.
- v The ENG team member(s) focuses on the hardware design processes, including the validation and verification activities.
- v The PA/CM team member(s) focus on the PA and CM processes.
- v If CSTA, TS, Directorate, or HQ personnel are to be involved in the review, communicate the area where their expertise is needed, so that they can prepare and perform any necessary research prior to the review.

- 4.3 All team members should review the activities/questions for the appropriate SOIs (as listed in the Job Aid).

STEP 5: MEET WITH ALL TEAM MEMBERS PRIOR TO THE HARDWARE REVIEW TO DISCUSS INDIVIDUAL RESPONSIBILITIES (TEAM)

5.1 This is typically a short meeting the evening or morning prior to the review. The purpose of this meeting is for all of the team members to be introduced, get a feel for any “issues” at the company to be reviewed, answer any last minute questions, and discuss any questions raised during preliminary review of documents.

Note: In some cases, a telecom works for this pre-review discussion; particularly when the team is spread over geographical distances.

Special Considerations for the Desk Review

- ⊖ When notifying the applicant of the review, make arrangements for when and where data should be sent. Also, specify the number of copies needed.
- ⊖ Establish a Point of Contact (POC) at applicant’s facility in case questions arise during the desk review.
- ⊖ Consider setting up a telecon or webcast with the applicant at the end of each day or keep a log of questions to fax the applicant since in-person interviews won’t be possible.

TASK 2: Performing the Hardware Review and Documenting Compliances, Findings, and Observations

The purpose of this task is to conduct all activities necessary to complete the review; document compliances, findings, and observations; and determine next steps.

STEP 1: CONDUCT ENTRY BRIEF WITH APPLICANT AND FAA TEAM (TEAM LEADER)

- 1.1 Introduce the review team members.
- 1.2 State the purpose of the review (summarize from the notification letter).
- 1.3 Review the agenda with the applicant and the appropriate personnel that need to be at each stage of the review.
- 1.4 Strive to create a good working partnership.

STEP 2: PRESENT OVERVIEW OF APPLICANT'S SYSTEM, HARDWARE, AND DESIGN PROCESS (APPLICANT AND TEAM)

- 2.1 Applicant presents program overview, description of the hardware to include its functions, system architecture; failure modes, hardware design assurance level, safety monitoring and protection mechanisms, and system and software interfaces, overall design organization structure and Findings/Observations from internal reviews.

Note: The review team should take care that a significant portion of the time allotted for the review is not taken up by the applicant's overview. This could result in a situation that is sometimes referred to as "compliance finding by presentation". Adequate time must be left for the review team to examine actual artifacts and data.

- 2.2 During the applicant's presentation, the FAA review team focuses on those issues/processes compatible with their expertise. For example:
 - v ENG team member focuses on the hardware design process (and related validation and verification activities) and technical issues.
 - v PA/CM team member focuses on implementation of PA and CM processes.
 - v The depth of the applicant's overview will depend on the SOI and whether or not the review team is familiar with the process (e.g., if this is a second review with the same team, the presentation may only be a memory jogger).

- 2.3 The review team assures that the applicant's presentation provides adequate information to give insight into the company's processes and procedures.
- v The review team members ask as many questions as needed to understand the project being reviewed.
- 2.4 The applicant's overview is generally limited in time to allow for adequate time to review data. **Note:** The team leader should work to keep the review on schedule.

STEP 3: REVIEW APPLICANT'S HARDWARE DATA AND INTERVIEW THE APPROPRIATE PERSONNEL (TEAM)

- 3.1 Part 3 of this Job Aid provides a summary of activities to be performed and questions to be answered during a review. The particular SOI being reviewed dictates which table is referenced. If the review is a combination of SOIs, multiple SOI Evaluation Activities tables (e.g. Table 5, 6, 7, 8) from Part 3 should be used.
- 3.2 The activities/questions outlined in Part 3 are a guide. There may need to be more or less activities/questions, depending on the nature of the project. Also, the sequence of activities/questions is flexible. The goal of the Job Aid is to provide a standardized approach for getting started. This includes sufficient guidance to cover most situations. Each hardware project will have unique aspects that are impossible to capture in a Job Aid. If there is anything that is not understood during the review, the review team should question the applicant further.

STEP 4: DOCUMENT THE HARDWARE REVIEW COMPLIANCES, FINDINGS, AND OBSERVATIONS (TEAM)

- 4.1 Document the Compliances, Findings, and Observations in detail. (Compliance indicates that the objective is satisfied; a Finding indicates non-compliance to a DO-254 objective; and an Observation identifies process improvement.) Throughout the review, each team member should take notes on what documents (number, revision level, date) were reviewed, what threads were traced, areas of concern or non-compliance to DO-254 objectives, discussions with applicant, and any other significant issues.

The review Compliances, Findings, and Observations are included in the exit briefing and final report and must be documented in enough detail that they could be found again in another review (i.e., reviews must be repeatable).

STEP 5: MEET AT THE END OF EACH DAY TO ASSESS PROGRESS, SUMMARIZE AND DOCUMENT COMPLIANCES, FINDINGS, AND OBSERVATIONS, AND PLAN FOR THE NEXT DAY (TEAM)

- 5.1 The team leader should keep a list of Compliances, Findings, and Observations based on input from team members. (Team Leader)
- 5.2 Team members should discuss any concerns, questions, etc. (Team)
- 5.3 The team should plan activities for the next day. (Team)

Note: The “end-of-the-day” meeting should be held in privacy to discuss issues openly (i.e., this meeting typically excludes the development team). Designees should be involved in the “end-of-day” meetings. During these meetings, the team may consider starting the DO-254 Compliances/Findings/Observations table, if time permits. (This will save time required for follow-up activities.)

Special Considerations for the Desk Review

- ⊖ The entry brief and any interim meetings to assess progress would only be a discussion among the review team members since the review is not on-site.
- ⊖ The applicant would not present the program overview—this information will be obtained by reading documents.
- ⊖ It will not be possible to interview personnel; however, you may want to keep a list of questions to fax or e-mail to the applicant or discuss via telephone.

TASK 3: Preparing and Conducting Exit Briefing

The purpose of this task is to summarize Compliances, Findings, and Observations and to share them with the applicant. The exit briefing addresses all issues related to DO-254 compliance, other related issues, and next steps.

STEP 1: PREPARE FOR THE BRIEFING BY HAVING A REVIEW TEAM MEETING (TEAM)

- 1.1 Discuss Compliances/Findings/Observations and agree on recommended action.
- 1.2 Present individual team member Compliances, Findings, and Observations and agree on how to debrief the applicant.
- 1.3 Summarize individual team member Compliances, Findings, and Observations in sufficient detail for incorporation into the report.
- 1.4 Prepare summary of issues based on “end-of-day” meetings.
- 1.5 Organize presentation order for the exit briefing and agree on who will present. (Sometimes the team leader will brief all Compliances/Findings/Observations. Sometimes individual team members will brief their particular Compliances/Findings/Observations.)

STEP 2: PRESENT EXIT BRIEFING (TEAM)

- 2.1 Provide introduction to exit briefing. (Team Leader)
 - √ Thank the applicant for the cooperation extended.
 - √ Be attentive to the applicant’s organizational environment and its concerns and issues.
 - √ Present information in an objective, positive manner.
 - √ Give an overview of the review’s purpose and briefing content.
 - √ Compliment/thank designees, applicant, hardware developer, as appropriate.
- 2.2 Present Compliances, Findings, and Observations in relationship to DO-254 objectives. (Team or Team Leader, as appropriate) **Note:** Some review teams, in addition to Findings and Observations, also use action items as a way to capture the results of their review. This is an acceptable approach IF action items are used appropriately. Action items should not be used as a means of avoiding documentation of Findings of non-compliance. Non-compliance to DO-254 objectives should be categorized as Findings. Action items should be limited in nature, such as requests for additional/ clarifying information or to schedule the date of a future SOI.

- 2.3 Summarize all issues that may be relevant to certification and compliance. (Team Leader)
- 2.4 Summarize any future action that must be taken to complete the project (e.g., another review may be required to determine progress or the designees may need to perform an in-house review). (Team Leader)
- 2.5 Inform applicant that a report will be prepared by the FAA and sent with a letter to summarize and document Findings, Observations, etc. (Team Leader)

Special Considerations for the Desk Review

- ⊖ A briefing or summary of the review should still be prepared; however, the delivery may be via telecon, webcast, or written report.

TASK 4: Conducting Follow-up Activities

The purpose of this task is to perform follow-up activities after the review. This may include telecons or additional reviews with the applicant. A report of the hardware review compliances, findings, and observations is prepared, coordinated, and sent to the applicant.

STEP 1: PREPARE REPORT (TEAM LEADER)

- 1.1 Based on the team members' inputs at the review, prepare a report on the results of the review:
 - v Summarize all data reviewed.
 - v Include a description of the difference between **Finding** and **Observation**.
 - v Summarize compliances/findings/observations, e.g., in "Summary of Compliances/Findings/Observations" tables found in Part 4.
- 1.2 Coordinate the report with review team members.
 - v Complete no later than one week after the review so that a timely response is given to applicants.
 - v Work portions of the report at "end-of-day" meetings.
 - v Prepare report depth and length as appropriate to the situation.

STEP 2: COORDINATE PRELIMINARY FINDINGS AND OBSERVATIONS WITH APPLICANT (TEAM)

- 2.1 Provide a draft report to the applicant requesting they identify and respond to issues on which they do not agree.
- 2.2 Reconcile discrepancies with the applicant (via telecon, e-mail, etc.).
- 2.3 Modify the report, as appropriate.

STEP 3: DETERMINE FUTURE ACTIVITIES (TEAM LEADER)

- 3.1 Determine if there will be a need for another review.
- 3.2 Identify activities that the applicant must address to show compliance.
- 3.3 If project is being reviewed by an organization delegation, determine if there is any need to communicate with any FAA personnel.
- 3.4 Determine if issue papers need to be drafted.

STEP 4: PREPARE A LETTER TO THE APPLICANT AND SUBMIT FINAL REPORT (TEAM LEADER)

- 4.1 Address certification and non-compliance issues in the letter.
- 4.2 Attach the review report and summary on non-compliance Findings.
- 4.3 Describe future steps required by the applicant.
- 4.4 Summarize future activities/expectation/plans (e.g., is a follow-up review required? Should designees perform reviews?)
 - v Place a copy of the letter in the project file.

STEP 5: COORDINATE WITH CERTIFICATION TEAM (TEAM)

- 5.1 Discuss appropriate issues with the Project Manager, other engineers, flight test, Principal Inspector, other managers, etc. for the certification project.
- 5.2 Create issue papers, special conditions, etc. with the assistance of CSTAs, TSs, Directorate personnel, HQ personnel, as appropriate.
- 5.3 Address any non-US certification issues, such as the creation of Certification Review Items (CRI), reporting on review activities, joint validation issues, etc.

Special Considerations for the Desk Review

- ⦿ Since the applicant was not present during the review and did not have a chance to address concerns, it is important to set up a telecon, webcast, or meeting to address all issues and questions prior to the submittal of the report.

PART 3 - ACTIVITIES FOR EACH STAGE OF INVOLVEMENT

The following pages highlight the activities and questions to be performed by the hardware review team at each SOI. These activities/questions may vary slightly for a desk review (e.g., you won't be able to interview developers for the desk review).

As emphasized before, these activities/questions are only to be used as a guide. Different situations may require the deletion or addition of activities/questions. For example, you may combine two SOIs, add questions, or delete activities.

Each SOI has a table summarizing the activities and questions that support that activity, with a tie to the relevant DO-254 objectives. Review teams typically divide the activities and questions among team members, as appropriate.

3.1 ACTIVITIES FOR STAGE OF INVOLVEMENT #1 – PLANNING REVIEW

Purpose	<ul style="list-style-type: none"> ⊞ To assess the interfaces with the system development process, software development process, and system safety assessment process; to review the system architecture; to assess the assigned hardware levels; and to determine the appropriateness of any system and hardware safety features and safety monitoring hardware and protection mechanisms for supporting systems reliability, integrity, safety, functionality, performance, and operability requirements (safety objectives). ⊞ To assess the applicant’s plans and standards in relationship to identified hardware level, safety features, and safety-related hardware requirements. ⊞ To ensure that plans and standards meet objectives identified in DO-254, and that the hardware will comply with other applicable hardware policy and guidance. ⊞ To assess that, when the applicant follows their plans, they will meet all applicable DO-254 objectives and other applicable hardware policy or guidance.
When Review Occurs	Shortly after completion of the hardware planning process, or any other necessary point. Plans and standards may not be fully completed; however, they should be fairly mature prior to the review and under configuration control.
Data Reviewed Prior to Review	Plan for Hardware Aspects of Certification (PHAC), Hardware Verification/Validation Plan (HVP), Hardware Design Plan (HDP), Hardware Configuration Management Plan (HCMP), Hardware Process Assurance Plan (HPAP), tool qualification plans, and other data, as applicable.
Data Reviewed at Review	PHAC, HVP, HDP, HCMP or HPAP, tool qualification plans as applicable, findings/observations/issues from pre-review activities (highly recommended) by designees/applicants/developers, hardware design standards, safety assessment, system architecture, hardware level justification, safety features, company policy and work instructions referenced in the plans and standards, and other data deemed necessary.

**Number of Days
Required** 1-3 days

**Evaluation Activities
and Questions** Table 5 provides typical activities and questions for SOI #1.

- Instructions**
- ⊖ There are eight major evaluation activities for Stage of Involvement #1: Planning Review.

 - ⊖ Review the questions for each activity in relationship to its corresponding DO-254 objective and hardware level.

Table 5. SOI #1 Evaluation Activities

Item #	SOI #1 Evaluation Activity/Question	Related DO-254 objective(s)
1.1	Review all plans (PHAC, HCMP, HPAP, HDP, HVP, tool qualification plans, etc.) and standards. Based on your review of all the plans, consider the following questions:	
1.1.1	Has the planning data been signed and put under CM (HC1 or HC2 as appropriate for the hardware level)? Verify there is objective evidence of coordination (e.g., authorized signatures) from all organizations controlled and affected by the hardware plans and standards.	<ul style="list-style-type: none"> • 4.1(1,2,3,4) • 7.1(1,2,3)
1.1.2	Are plans, standards, design and verification environments cited complete, clear, and consistent (e.g., can the design and verification engineers follow them)?	<ul style="list-style-type: none"> • 4.1(1,2,3)
1.1.3	Do the plans and standards address the content as specified in DO-254 section 10 (i.e., sections 10.1.1 through 10.1.6)? <u>Note:</u> The plans and standards are not required to be packaged as identified in 10.1.1 through 10.1.6; however, the items specified in 10.1.1 through 10.1.6 should be documented somewhere in the plans and standards.	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
1.1.4	Do the plans and standards address the hardware change process and procedures modifying the hardware and tools (if tools are used)?	<ul style="list-style-type: none"> • 4.1(1) • 7.1(3)
1.1.5	Are all hardware tools identified in the plans and does the tool assessment provide rationale included for why each does or does not need to be qualified?	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
1.1.6	Are the inputs, activities, transition criteria, and outputs specified for each process (including identification of sequencing and feedback mechanisms)?	<ul style="list-style-type: none"> • 4.1(1)
1.1.7	Are the proposed design methods defined and explained (including identification and rationale of the proposed validation and verification methods)?	<ul style="list-style-type: none"> • 4.1(1,4)
1.1.8	Is there evidence that appropriate planning process activities have been adequately performed to meet the planning process objectives will be met? (Refer to section 4.2 of DO-254)	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
1.1.9	If the plans and standards are followed, would this ensure that all applicable DO-254 objectives are met (i.e., do the plans and standards address how each of the applicable DO-254 objectives will be satisfied)?	<ul style="list-style-type: none"> • All objectives

Item #	SOI #1 Evaluation Activity/Question	Related DO-254 objective(s)
1.1.10	<p>Are the interfaces and communication channels with the hardware design processes addressed in the plans and well defined? Evaluate processes for flow down of system requirements (functional, performance, operational, safety-related, and system architecture safety features) and for clarifying ambiguous system requirements. Determine if the hardware verification process will be claiming “formal test credit” for testing conducted by the system verification and validation processes. If so, then what kind of credit, and how much credit will be granted?</p>	<ul style="list-style-type: none"> • 4.1(1,3)
1.1.11	<p>Are the interfaces and communication channels with the system safety assessment process addressed in the plans and well defined? Evaluate the flow down of safety-related requirements and safety objectives from the system safety assessment (SSA) process to the hardware processes, and the feedback of derived requirements to the SSA process for evaluation.</p>	<ul style="list-style-type: none"> • 4.1(1,3)
1.1.12	<p>Are the interfaces and communication channels with applicable hardware design and verification processes addressed in the plans and well defined? Evaluate the processes for documenting and communicating hardware dependencies and interactions with the system software and its development and verification processes, and for software dependencies on the hardware and its design and verification processes. Determine the process used to convey safety features (e.g., monitors, built in test, memory management unit, I/O device, processor features (cache, registers, priorities, schedulers, supervisor/user modes, etc.)) and software changes affecting the hardware processes, and how the hardware processes will address them.</p>	<ul style="list-style-type: none"> • 4.1(1,3)
1.1.13	<p>Are there unique additional considerations associated with the project (unique alternative means or methods of compliance, unique approaches to design, verification, CM, PA), proposals that don't comply with FAA national or Directorate policy or issue papers, etc.? If so:</p> <ul style="list-style-type: none"> • Have national or directorate hardware and systems personnel reviewed and approved any unique additional considerations? • Is rationale for acceptance or rejection of developer/applicant's proposals well documented? 	<ul style="list-style-type: none"> • 4.1(4)
1.1.14	<p>Are issue papers or national/directorate policy required for any of the additional considerations? If so, do the plans and standards address how compliance with the issue papers and/or national/directorate policy will be achieved?</p>	<ul style="list-style-type: none"> • 4.1(4)

Item #	SOI #1 Evaluation Activity/Question	Related DO-254 objective(s)
1.1.15	Have all foreign certification issues (e.g., certification review items, certification action items, review findings/issues/actions, etc.) been addressed (if a joint certification or validation project)? Additionally, do the plans and standards address how the foreign certification authority issues and concerns will be addressed?	<ul style="list-style-type: none"> • 4.1(4)
1.1.16	Are the means of compliance of the hardware design assurance objectives defined and are they commensurate with the design assurance level(s)?	<ul style="list-style-type: none"> • 4.1(4)
1.2	Determine if additional considerations defined in Section 11 of DO-254 have been documented and addressed in the plans. Consider the following questions:	
1.2.1	Are such items as previously developed hardware, commercial-off-the shelf (COTS) hardware or COTS Intellectual Property, field-loadable logic, option-selectable hardware, product service experience, alternative methods of compliance, etc. identified and addressed in the plans?	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
1.2.2	<p>If the developer plans on using previously developed hardware (PDH) for the current design, consider the following questions:</p> <ul style="list-style-type: none"> • If PDH from legacy systems is intended to be used, does the service experience of the system support reuse of its hardware? • Are there any airworthiness directives, service bulletins, in-work National Transportation Safety Board safety recommendations, or unresolved problem reports with safety, functional, performance, operational or maintenance issues for the legacy system or any proposed PDH? • Does the PDH have a satisfactory service experience? • Does the developer intend to make any modifications to PDH? Are plans and processes defined for managing, controlling, and verifying those changes (in compliance with DO-254 section 11.3, 11.3.1-11.3.3)? • Is the PDH or legacy hardware used in an identical manner and executed on the same system hardware and in the same environment as its previous uses? • Was the PDH previously approved to DO-254? 	<ul style="list-style-type: none"> • 4.1(1,2,3,4)

Item #	SOI #1 Evaluation Activity/Question	Related DO-254 objective(s)
1.2.3	<p>Verify that hardware tools are identified and explained in the plans. Consider the following questions:</p> <ul style="list-style-type: none"> • Do the plans provide rationale for why tools do or do not need to be qualified (e.g., was the tool assessment and qualification process in section 11.4.1 discussed in the plans)? • Is service experience claimed for the use of any tool? If so, has the tool changed or is it being used in the same way as previously used? Does the documented tool service experience justify and support the intended use for the current design? 	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
1.2.4	<p>Are tools to be qualified supported with a tool qualification plan (either in the PHAC or in a separate document)? Verify that tools are properly categorized into design or verification or multi-function tools. Verify that the plan for assessment and qualification of tools is documented and adequate for the specified tool use.</p> <p>Note: Section 11.4 of DO-254 provides specific guidelines regarding tool qualification.</p>	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
1.2.5	<p>Is reverse engineering being planned for any PDH? If so:</p> <ul style="list-style-type: none"> • Has the rationale for reverse engineering been documented and adequately justified to the certification authority (typically in the “additional considerations” section of the PHAC)? • Has the reverse engineering effort been planned (in the PHAC and other plans)? • Are processes and procedures well defined? • Is the reverse engineering life cycle documented? • Does the reverse engineering approach meet DO-254 objectives? • How will the requirements be created? Is the plan adequate? • Do transition criteria and traceability exist? Are they adequate? <p>Note: See CAST-18, Reverse Engineering in Certification Projects, for specific certification concerns regarding reverse engineering. In some cases, an issue paper may be required, if the plans do not address the DO-254 objectives compliance. Available at: http://www.faa.gov/aircraft/air_cert/design_approvals/air_software/cast/</p>	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
1.3	Review PHAC and consider the following questions:	

Item #	SOI #1 Evaluation Activity/Question	Related DO-254 objective(s)
1.3.1	<p>Does the PHAC adequately address the proposed contents described in DO-254, Section 10.1.1? If not, where are the contents documented?</p> <p>Note: If it is documented in another planning document, that document will need to be evaluated before the PHAC can be approved. Also, that data item should be configuration controlled to the same HC1 level as the PHAC.</p>	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
1.3.2	<p>Does the PHAC address the following questions regarding changes to plans and standards:</p> <ul style="list-style-type: none"> • Is a process in place to address changes to plans and standards that may occur throughout the design process? • Are there plans and processes to address any deviations to plans and standards? • Do the deviations require justification and rationale for why they are acceptable for this project? • Will applicable aspects of the hardware plans, standards and procedures be conveyed to any sub-tier suppliers of components of the system and subcontractors to ensure their compliance to the approved plans, standards and procedures? • Are the plans and standards under change control? 	<ul style="list-style-type: none"> • 4.1(1,2,3,4) • 7.1(1,2,3)
1.3.3	<p>Does the hardware level proposed in the PHAC support the system safety assessment adequately? If the hardware level is lower than what the system safety assessment suggests, is there adequate justification (e.g., through FFPA, system architecture, safety feature, redundancy, fail safe design techniques, partitioning as described in Appendix B of DO-254)?</p> <p>Note: This determination will likely require input from the systems engineer.</p>	<ul style="list-style-type: none"> • 4.1(4)
1.3.4	<p>Does the PHAC address the additional and applicable considerations described in Appendix B of DO-254?</p>	<ul style="list-style-type: none"> • 4.1(4)
1.3.5	<p>Does the PHAC define independence and describe the method for independence required for Level A and B hardware?</p>	<ul style="list-style-type: none"> • 4.1(4)
1.4	Review HDP and consider the following questions:	

Item #	SOI #1 Evaluation Activity/Question	Related DO-254 objective(s)
1.4.1	If the HDP is followed, will the applicable DO-254 design processes objectives be met?	<ul style="list-style-type: none"> • 4.1(1) • 5.1.1(1,2,3) • 5.2.1(1,2,3) • 5.3.1(1,2,3) • 5.4.1(1,2,3) • 5.5.1(1,2,3)
1.4.2	Does the HDP adequately address the proposed contents described in DO-254, Section 10.1.2? If not, are the contents included in another plan?	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
1.4.3	Are the hardware design processes defined in sufficient detail to ensure proper implementation of the hardware life cycle processes and model proposed for the project? Are transition criteria clear and enforceable?	<ul style="list-style-type: none"> • 4.1(1)
1.4.4	Will applicable aspects of the HDP, development environment, standards and processes be conveyed to any sub-tier suppliers of components of the system and subcontractors to ensure their compliance to the approved plans, standards, and procedures?	<ul style="list-style-type: none"> • 4.1(1,2,3)
1.4.5	<p>Has the hardware development environment been adequately defined (e.g., documentation tools, requirements definition and capture tools, traceability tools, design tools (including architecture, derived requirements definition and capture tools, HDL coding tools, integration tools, development host computer environment, tools to ensure protection of baselined hardware life cycle data such as configuration management and control tools, access privileges, etc.)? Additionally:</p> <ul style="list-style-type: none"> • Are tool users' guides, restrictions, and limitations available and known by the hardware developers using them? • Do any of the tools support enforcement of the hardware description languages (HDL) standards, transition criteria, data baselining and approval process, etc.? For example: (1) does the HDL code editor tool or compiler enforces any coding rules, restrictions, or limitations? (2) does the document control (CM system) enforce access privileges to data and ensure no unauthorized changes to baselined data? 	<ul style="list-style-type: none"> • 4.1(2,3)

Item #	SOI #1 Evaluation Activity/Question	Related DO-254 objective(s)
1.4.6	<p>What kind of synthesis tool is being proposed? Does the applicant have experience with the synthesis tool? Have the synthesis tool's options and optimization been identified? Have the errata sheets, vendor problem notices bulletins, or vendor problem reports for the synthesis tool been reviewed and analyzed for safety impact on the operation of the tool? If safety impacts have been identified, then have the mitigations been implemented and documented for the synthesis tool?</p> <p>Note: Changes to synthesis tool's options and optimization may invalidate previous tests and coverage analysis.</p>	<ul style="list-style-type: none"> • 4.1(3)
1.4.7	<p>Are HDL coding and design standards defined?</p> <p>Note: Some HDL constructs may produce non-deterministic results and therefore may not meet the objectives of DO-254.</p>	<ul style="list-style-type: none"> • 4.1(2)
1.5	Review the HCMP and consider the following questions:	
1.5.1	If the HCMP is followed, will the applicable DO-254 configuration management objectives be satisfied?	<ul style="list-style-type: none"> • 4.1(1) • 7.1(1,2,3)
1.5.2	Does the HCMP adequately address the proposed contents described in DO-254, Section 10.1.5?	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
1.5.3	Will applicable aspects of the HCMP, environment, tools, training and procedures be conveyed to any sub-tier suppliers of components of the system and subcontractors to ensure their compliance to the approved plans, standards and procedures?	<ul style="list-style-type: none"> • 4.1(1,2,3)
1.6	Review the HPAP and consider the following questions:	
1.6.1	If the HPAP is followed, will the process assurance objectives be satisfied?	<ul style="list-style-type: none"> • 4.1(1) • 8.1(1,2,3)
1.6.2	Does the HPAP adequately address the proposed contents described in DO-254, Section 10.1.6? If not, are the contents included in another plan?	<ul style="list-style-type: none"> • 4.1(1,2,3)
1.6.3	Is hardware PA independent from the development organization to a sufficient degree to ensure that PA has the autonomy and authority to ensure PA audit findings, actions, and deficiencies will be corrected?	<ul style="list-style-type: none"> • 8.1(1,2,3)
1.6.4	Are there any deviations proposed for this project from the PA plans and procedures? If so, are those deviations identified and justified?	<ul style="list-style-type: none"> • 7.1(3) • 8.1(3)
1.6.5	Are the transition criteria, interrelationships, and sequences among process properly and adequately defined, and are they capable of being audited to ensure process compliance?	<ul style="list-style-type: none"> • 4.1(1) • 8.1(1)

Item #	SOI #1 Evaluation Activity/Question	Related DO-254 objective(s)
1.6.6	Are there defined procedures for how PA audit findings, actions, and observed deficiencies will be corrected for the project?	<ul style="list-style-type: none"> • 4.1(1)
1.6.7	Is the PA findings process a separate process or does it use different tools for issues resolution than the development organization (i.e., how are the PA and development team problems reported)?	<ul style="list-style-type: none"> • 4.1(1)
1.6.8	<p>Are the criteria for PA involvement (sampling, attending reviews, evaluation, conducting process compliance audits, witnessing tests, “conforming” environments, etc.) defined to ensure that life cycle objectives are met?</p> <p>Note: Criteria for involvement may be dependent on the hardware level or novelty of the product being developed.</p>	<ul style="list-style-type: none"> • 4.1(1)
1.6.9	Has a person or organization responsible for each documented PA process and activity been identified?	<ul style="list-style-type: none"> • 8.1(1,2,3)
1.6.10	Will applicable aspects of the HPAP, environment, tools, training, and procedures be conveyed to any sub-tier suppliers of components of the system and subcontractors to ensure their compliance to the approved plans, standards, and procedures?	<ul style="list-style-type: none"> • 4.1(1,2,3)
1.7	Review the HVP (Validation/Verification) and consider the following questions:	
1.7.1	If HVP is followed, will DO-254 validation and verification objectives be met?	<ul style="list-style-type: none"> • 4.1(1) • 6.1.1(1,2,3) • 6.2.1(1,2,3)
1.7.2	Does the HVP adequately address the proposed contents described in DO-254, Section 10.1.3 & 10.1.4? If not, are the contents included in another plan?	<ul style="list-style-type: none"> • 4.1(1,2,3)
1.7.3	Will applicable aspects of the HVP plan, environment, tools, training and procedures be conveyed to any sub-tier suppliers of components of the system and subcontractors to ensure their compliance to the approved plans, standards, and procedures?	<ul style="list-style-type: none"> • 4.1(1,2,3)
1.7.4	Does the HVP describe how independence will be achieved, when required?	<ul style="list-style-type: none"> • 4.1(1)

Item #	SOI #1 Evaluation Activity/Question	Related DO-254 objective(s)
1.7.5	<p>Does the HVP describe the verification method used for each hardware verification activity? Specifically:</p> <ul style="list-style-type: none"> • Are methods, checklists, tools and procedures described for conducting reviews of hardware requirements, design, coding, and integration? • Are methods, checklists, tools and procedures described for conducting analyses of traceability, change impact, timing, verification coverage, normal range coverage, robustness test coverage, etc.? <p>Note: Robustness testing does not appear as an objective for DO-254, but its application has shown to be effective for other domains (e.g., software).</p> <ul style="list-style-type: none"> • Are methods, checklists, tools and procedures described for conducting reviews of test plans, test procedures, test cases, and test results? • Are methods, checklists, tools and procedures described for conducting testing of hardware requirements, hardware derived requirements, hardware integration, hardware-software integration, normal range, and robustness? • If hardware verification test credit will be claimed for testing conducted on system benches, laboratory, integrated system facilities, do the plans and procedures describe how those activities will be conducted and hardware test results and coverage analyses documented? • Is there a well-defined process and procedure for ensuring that deficiencies detected during the testing process will be conveyed to and corrected by the hardware design process and team? 	<ul style="list-style-type: none"> • 4.1(1,2,3)

Item #	SOI #1 Evaluation Activity/Question	Related DO-254 objective(s)
1.7.6	<p>Does the HVP adequately describe the verification environment (e.g., tools, test equipment, etc.)? Consider the following questions:</p> <ul style="list-style-type: none"> • Are there any automated tools? If so, do any of the tools need to be qualified? • Is there any overlap between various kinds of testing (e.g., overlap of system and hardware requirements-based testing)? • Is the division of the testing task between suppliers and sub-contract suppliers adequately addressed and controlled? 	<ul style="list-style-type: none"> • 4.1(1,2,3)
1.7.7	<p>Are verification plans, including test plans, and procedures conveyed to suppliers and sub-contractors to ensure their activities and results will comply with the approved plans and procedures?</p>	<ul style="list-style-type: none"> • 4.1(1,2,3)
1.7.8	<p>Does the HVP describe methods for test case selection? Does the HVP specify how each requirement will be tested (e.g., hardware component test, board level/hardware integration test, hardware/software integration test)?</p>	<ul style="list-style-type: none"> • 4.1(1,2,3)
1.7.9	<p>Does the HVP or procedures specify who is allowed to perform verification tasks?</p>	<ul style="list-style-type: none"> • 4.1(1)
1.7.10	<p>If verification tools are used, has the tool assessment process as described in section 11.4 of DO-254 been followed?</p> <p>Note: See section 11.4 of DO-254 for more information on tool assessment and qualification process.</p>	<ul style="list-style-type: none"> • 4.1(1,3)
1.8	Review the hardware design standards and consider the following questions:	
1.8.1	<p>Are the hardware design standards (Requirements Standards, Hardware Design Standards, Validation and Verification Standards, and Hardware Archive Standards) identified and well defined?</p>	<ul style="list-style-type: none"> • 4.1(2)
1.8.2	<p>Are the hardware design standards consistent with the plans and do they support implementation of the plans?</p>	<ul style="list-style-type: none"> • 4.1(2)
1.8.3	<p>Will the hardware design standards support the proposed hardware level(s) and hardware’s compliance with DO-254 objectives?</p>	<ul style="list-style-type: none"> • 4.1(2,4)
1.8.4	<p>Have standards been verified for each defined hardware life cycle process? Are the standards adequate to support the hardware level?</p>	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
1.8.5	<p>Have standards been described in detail to support the planning process objectives (see sections 10.2.1, 10.2.2, 10.2.3 and 10.2.4)?</p>	<ul style="list-style-type: none"> • 4.1(1,2,3,4)

Item #	SOI #1 Evaluation Activity/Question	Related DO-254 objective(s)
1.8.6	If HDL or another hardware design language is used, have coding standards been verified to ensure that any constructs are not permitted which would invalidate the assumptions about the safety levels (e.g., non-determinism)?	<ul style="list-style-type: none"> • 4.1(2)
1.8.7	Have the hardware design standards been verified to ensure that there are limitations, prohibitions, and constraints to not permit the use of design and code features that are not deterministic and not verifiable?	<ul style="list-style-type: none"> • 4.1(2)
1.8.8	<p>What HDL is being used?</p> <ul style="list-style-type: none"> • Does the applicant have experience with the language? • Does the HDL have any features or capabilities that may be difficult to verify? Has the applicant or developer imposed any prohibitions or restrictions on the use of these features in the coding standards and/or review checklists? Does the applicant/developer have plans and procedures established for how these features will be verified? • What features of the HDL support or hinder real-time implementation and verification? • Are any HDL problems documented and addressed? • Has a safe sub-set of the HDL been selected? How will it be verified that that safe sub-set was adhered to (e.g., code reviews, checklists, testing, etc.)? • What are common errors of the HDL? Do coding standards protect against these errors? 	<ul style="list-style-type: none"> • 4.1(1,2,3)

3.2 ACTIVITIES FOR STAGE OF INVOLVEMENT #2 – DESIGN REVIEW

Purpose	<ul style="list-style-type: none"> ⊗ Assess effective implementation of applicant’s plans and standards through examination of hardware life cycle data. ⊗ Assess and agree to any changes in the plans. ⊗ Assure that hardware life cycle data meets DO-254 objectives.
When Review Occurs	<p>When the hardware design is sufficiently mature to support ongoing hardware change without degrading safety or architecture, or when deemed necessary. Some things that should be in place prior to this review are:</p> <ul style="list-style-type: none"> ⊗ Hardware requirements are documented, reviewed, and traceable to system requirements. ⊗ Detailed Design Data (e.g., HDL, RTL, schematic capture, C) implements, and is traceable to, the hardware requirements and has been reviewed.
Data Reviewed Prior to Review	<p>Report from Stage of Involvement #1 (SOI #1); open items from SOI #1; and all plans (PHAC, HVP (Validation/Verification), HDP, HCMP, HPAP (as a refresher after SOI #1 or to review changes to plans since SOI #1)).</p>
Data Reviewed at Review	<p>Standards for Hardware Requirements, Design, and Code; Hardware Requirements; Hardware Design Description; Detailed Design Data; Hardware Validation and Verification Results; Problem Reports; Hardware CM Records; Hardware Quality Assurance Records; Trace Matrix/Tool; and Designees’ findings/observations from pre-review activities.</p>
Number of Days Required	<p>1-3 days</p>

Evaluation Activities and Questions

During Stage of Involvement #2 (SOI #2), a trace matrix or similar traceability tool should be used to perform one or two top-down traces (from system requirements to hardware requirements to design description to detailed design to test cases) and one or two bottom-up traces (from detailed design to design description to hardware requirements to systems requirements) in each of the major sub-systems. The traces should be performed in different areas (e.g., display, interface, core logic, built-in test). Table 6 provides typical activities and questions for SOI #2.

Instructions

- ⊖ There are six major evaluation activities for Stage of Involvement #2: Design Review.
- ⊖ Review the questions for each activity in relationship to its corresponding DO-254 objective and hardware level.

Table 6. SOI#2 Evaluation Activities

Item #	SOI #2 Evaluation Activity/Question	Related DO-254 objective(s)
2.1	Review status from SOI #1.	
2.1.1	Have all issues and Findings from SOI #1 been satisfactorily addressed? If not, then has justification or rationale been given?	<ul style="list-style-type: none"> • 4.1(1,2,3,4)
2.2	Review the requirements capture process. Consider the following questions:	
2.2.1	Are the hardware requirements under HC1 configuration control?	<ul style="list-style-type: none"> • 7.1(1,2,3)
2.2.2	Have the hardware requirements been reviewed in accordance with the hardware validation/verification plans?	<ul style="list-style-type: none"> • 8.1(2)
2.2.3	<p>Are all hardware and derived requirement(s) associated with each selected system level requirement (i.e., identify threads between system and hardware requirements) clearly identified?</p> <p>Note: Use of a design trace matrix/tool may prove to be helpful.</p>	<ul style="list-style-type: none"> • 5.1.1(1,2,3) • 6.1.1(1) • 6.2.1(2)
2.2.4	If independence is required for the hardware level, is the person doing the verification different than the one responsible for developing the requirement(s)?	<ul style="list-style-type: none"> • Appendix A • 6.2.1(3)
2.2.5	Is each requirement (including derived) uniquely identified (i.e., each requirement number is truly only one requirement)?	<ul style="list-style-type: none"> • 5.1.1(1,2,3) • 7.1(1)
2.2.6	Are the requirements (including derived) unambiguous? Does the requirement have the same meaning to all participants (acquirer, systems engineer, hardware developers, and users)?	<ul style="list-style-type: none"> • 5.1.1(1,2,3) • 6.1.1(1)
2.2.7	Are requirements (including derived) consistent (e.g., terminology attributes, data definitions)?	<ul style="list-style-type: none"> • 5.1.1(1,2,3) • 6.1.1(1)
2.2.8	Are hardware requirements (that trace back to that system level requirement) accurate? That is, if all these requirements are met, would the associated system level requirement be satisfied? If not, determine if there are additional hardware requirements that if implemented, the combination of software and hardware requirements would satisfy the corresponding requirement.	<ul style="list-style-type: none"> • 5.1.1(1,2,3)
2.2.9	Are the requirements (including derived) complete? Are there any “To Be Determined” items in the requirements data?	<ul style="list-style-type: none"> • 5.1.1(1,2,3) • 6.1.1(1)

Item #	SOI #2 Evaluation Activity/Question	Related DO-254 objective(s)
2.2.10	<p>Is each requirement verifiable through testing, inspection, or analysis?</p> <p>Note: Timing, sizing, and partitioning requirements are generally supported through analysis.</p>	<ul style="list-style-type: none"> • 6.2.1(2,3)
2.2.11	<p>Does each requirement conform to applicable standards as defined in the developer's hardware requirement standards?</p>	<ul style="list-style-type: none"> • 4.1(2) • 5.2.1(1) • 5.3.1(1)
2.2.12	<p>If previous requirement verification results are being used to verify the current design (e.g., a "gold standard"), have the objectives for each selected requirement(s) been previously verified?</p>	<ul style="list-style-type: none"> • 6.2.1(1)
2.2.13	<p>Are there inconsistencies between the requirements reviewed and the hardware design plans?</p>	<ul style="list-style-type: none"> • 8.1(2)
2.2.14	<p>Do any interviews with the hardware developers indicate that the plans were not followed for requirements capture?</p>	<ul style="list-style-type: none"> • 8.1(1,2)
2.2.15	<p>Are derived requirements used accurately and consistently?</p>	<ul style="list-style-type: none"> • 5.1.1(2)
2.2.16	<p>Have the derived requirements been fed back to the safety assessment and/or other appropriate processes?</p>	<ul style="list-style-type: none"> • 5.1.1(2)
2.2.17	<p>Have errors and omissions in the hardware requirements been provided to the system development process for resolution?</p>	<ul style="list-style-type: none"> • 5.1.1(3)
2.3	<p>Review the hardware conceptual design process. Consider the following questions:</p>	
2.3.1	<p>Does the conceptual design data (including identification of major components, reliability and maintenance test features) adequately describe the hardware item's architecture and functional design?</p> <p>Note: Refer to 10.3.2.1 of DO-254.</p>	<ul style="list-style-type: none"> • 5.2.1(1)
2.3.2	<p>Is the conceptual design data under the appropriate configuration control?</p>	<ul style="list-style-type: none"> • 7.1(1,2,3)
2.3.3	<p>Is the conceptual design data traceable to the hardware requirements?</p>	<ul style="list-style-type: none"> • 6.2.1(2)
2.3.4	<p>Have the derived requirements, including any interface definitions, identified in the conceptual design process been fed back to the requirements capture process?</p>	<ul style="list-style-type: none"> • 5.2.1(2)

Item #	SOI #2 Evaluation Activity/Question	Related DO-254 objective(s)
2.3.5	Have requirement omissions and errors been fed back to the appropriate process for resolution?	<ul style="list-style-type: none"> • 5.2.1(3)
2.4	Review the detailed design process. Consider the following questions:	
2.4.1	<p>Is the detailed design data (including top-level drawings, assembly drawings, interface control drawings, hardware/software interface data, and any applicable architectural mitigation data such as safety monitors, dissimilarity, fault tolerant and test features) sufficient to implement the hardware item consistent with its requirements?</p> <p>Note: See 10.3.2.2 of DO-254.</p>	<ul style="list-style-type: none"> • 5.3.1(1)
2.4.2	Is the detailed design data traceable to the conceptual design and hardware requirements?	<ul style="list-style-type: none"> • 6.2.1(2)
2.4.3	Have the derived requirements, including any interface definitions, identified in the conceptual design process been fed back to the requirements capture process?	<ul style="list-style-type: none"> • 5.3.1(2)
2.4.4	Have requirement omissions and errors been fed back to the appropriate process for resolution? Is there a person or organization whose responsibilities ensure that any safety implications from these omissions and errors have been properly addressed?	<ul style="list-style-type: none"> • 5.3.1(3)
2.5	Review the hardware implementation process. Consider the following questions:	
2.5.1	Was the hardware item, which implements the detailed design, produced using representative manufacturing processes (where practical)?	<ul style="list-style-type: none"> • 5.4.1(1)
2.5.2	Are the hardware item implementation, assembly, and installation data complete?	<ul style="list-style-type: none"> • 5.4.1(2)
2.5.3	Is the hardware item implementation traceable to the detailed design data?	<ul style="list-style-type: none"> • 6.2.1(2)
2.5.4	Have the derived requirements (generated by the implementation process) been fed back to the detailed design process or other appropriate processes?	<ul style="list-style-type: none"> • 5.4.1(3)
2.5.5	Have requirement omissions and errors been fed back to the appropriate process for resolution?	<ul style="list-style-type: none"> • 5.4.1(4)
2.6	Review the Production Transition Process	
2.6.1	Has manufacturing data been produced and established from the configured design data for the implemented product?	<ul style="list-style-type: none"> • 5.5.1(1)

Item #	SOI #2 Evaluation Activity/Question	Related DO-254 objective(s)
2.6.2	Have changes or improvements incorporated during the production transition process been evaluated against product and safety requirements?	• 8.1(2)
2.6.3	Has the manufacturing data been checked for completeness and consistency with the configured design data?	• 8.1(2)
2.6.4	Has the manufacturing requirements related to safety been identified and documented and manufacturing controls established?	• 5.5.1(2)
2.6.5	Has the data required to develop acceptance test criteria been determined?	• 5.5.1(2)
2.6.6	Have the derived requirements (generated by the production transition process) been fed back to the implementation process or other appropriate processes?	• 5.5.1(3)
2.6.7	Have requirement omissions and errors been fed back to the appropriate process for resolution? Is there a person or organization whose responsibilities ensure that any safety implications from these omissions and errors have been properly addressed?	• 5.5.1(4)

3.3 ACTIVITIES FOR STAGE OF INVOLVEMENT #3 – VALIDATION AND VERIFICATION REVIEW

Purpose	<ul style="list-style-type: none"> ⊖ Assess effective implementation of the applicant’s validation/ verification plans and procedures. ⊖ Check the completion of all associated CM and PA tasks. ⊖ Make determination on acceptable deviations from plans and standards found during the review or with the applicant’s requested deviations. ⊖ Ensure that the selected hardware requirements have been validated and verified, as applicable. ⊖ Ensure that the hardware life cycle data meets DO-254 objectives. ⊖ Ensure that the verification activity satisfied the verification coverage requirements found in DO-254 Appendix B.
When Review Occurs	<p>When the following activities are in place (or when deemed necessary):</p> <ul style="list-style-type: none"> ⊖ Test procedures and results (if available) are documented and reviewed. ⊖ Detailed Design Data (e.g., HDL, RTL, schematic capture, C) satisfies hardware requirements. ⊖ A coverage analysis indicates that the requirements are met for levels A and B, per Appendix B of DO-254. <p>Note: Testing is where many applicants have problems. It is best to perform this review early enough that major retest will not be required if issues are found, but late enough to see some trends in the test program.</p>
Data Reviewed Prior to Review	<p>Reports from SOI #1 and SOI #2, open items from SOI #1 and SOI #2, and all plans (PHAC, HVP, HDP, HCMP, HPAP (as a refresher after SOI #1 & SOI #2 or to review changes to plans since SOI #1 & SOI #2)).</p>

Data Reviewed at Review	Hardware Requirements; Hardware Design Description; Detailed Design Data; Hardware Verification Cases and Procedures; Hardware Verification Results; Problem Reports; Hardware Configuration Management Records; Hardware Process Assurance Records; Trace Matrix/Tool; and Designees' findings/observations from pre-review activities.
Number of Days Required	1-3 days
Evaluation Activities and Questions	During SOI #3, a trace is performed on a sampling of system requirements allocated to hardware to see if they are adequately tested. Likewise, test cases are traced up to the system requirements to verify traceability. Table 7 provides typical activities and questions for SOI #3.
Instructions	<ul style="list-style-type: none">⊖ There are fourteen major evaluation activities for Stage of Involvement #3: Validation and Verification Review.⊖ Review the questions for each activity in relationship to its corresponding DO-254 objective and hardware level.

Table 7. SOI #3 Evaluation Activities

Item #	SOI #3 Evaluation Activity/Question	Related DO-254 objective(s)
3.1	Review status from SOI #1 and #2	
3.1.1	Have all issues and Findings from SOI #1 and SOI #2 been satisfactorily addressed? If not, then has justification or rationale been given?	<ul style="list-style-type: none"> • 4.1(1,2,3,4) • 5.1.1(1,2,3) • 5.2.1(1,2,3) • 5.3.1(1,2,3) • 5.4.1(1,2,3) • 5.5.1(1,2,3,4)
3.2	Review documented activities and artifacts against plans.	
3.2.1	Is there evidence that the HVP (Validation/Verification) and other plans related to verification, integration, and testing are being followed (e.g., progress against timeframes, staffing etc.)?	<ul style="list-style-type: none"> • 8.1(1,2)
3.3	Review validation of derived requirements. Consider the following questions:	
3.3.1	Are the derived requirements against which the hardware item is to be verified correct and complete?	<ul style="list-style-type: none"> • 6.1.1(1)
3.3.2	Have the derived requirements been evaluated for impact on safety and have the evaluations been documented?	<ul style="list-style-type: none"> • 6.1.1(2)
3.3.3	Have omissions and errors associated with derived requirements been fed back to the appropriate process for resolution and have they been documented accurately in problem reports? Is there a person or organization whose responsibilities ensure that any safety implications from these omissions and errors have been properly addressed?	<ul style="list-style-type: none"> • 6.1.1(3)
3.4	Sample the applicant’s test cases and consider:	
3.4.1	Are test cases traceable to the requirements?	<ul style="list-style-type: none"> • 6.2.1(2)
3.4.2	Are the requirements traceable to the detailed design (e.g., HDL, hardware schematics)?	<ul style="list-style-type: none"> • 6.2.1(2)
3.4.3	Have normal ranges been tested?	<ul style="list-style-type: none"> • 6.2.1(1)
3.4.4	Is robustness of the design adequately assessed by the test cases? Note: Robustness testing does not appear as an objective for DO-254, but its application has shown to be effective for other domains (e.g., software).	<ul style="list-style-type: none"> • 6.2.1(1)
3.5	Review test cases and procedures, considering the following questions:	
3.5.1	Have test cases and procedures been reviewed for correctness?	<ul style="list-style-type: none"> • 6.2.1(1,2,3)

Item #	SOI #3 Evaluation Activity/Question	Related DO-254 objective(s)
3.5.2	Do the test cases and procedures adhere to the relevant plans and standards? For example, have detailed design standards, especially those relevant to limitations of limitations related to advanced verification techniques (DO-254 Appendix B), been followed?	<ul style="list-style-type: none"> • 6.2.1(1)
3.5.3	Are the test cases and procedures appropriately commented?	<ul style="list-style-type: none"> • 6.2.1(1,3)
3.5.4	Have the test cases and procedures been subjected to appropriate change and configuration control?	<ul style="list-style-type: none"> • 7.1(1,2,3)
3.5.5	Is the purpose for each test case clearly explained?	<ul style="list-style-type: none"> • 6.2.1(1,2,3)
3.5.6	Is the separation between test cases clear? For example, is each test start and stop identified? This assists tracing the source of unexpected drops in coverage.	<ul style="list-style-type: none"> • 6.2.1(1,2,3)
3.5.7	Do the test cases and procedures specify required input data, sequence and test conditions (e.g., ambient temperature and applied voltage), and expected output data?	<ul style="list-style-type: none"> • 6.2.1(1,3)
3.5.8	Were the inputs for each test case derived from the requirements (as opposed to being derived from the HDL)?	<ul style="list-style-type: none"> • 6.2.1(1,3)
3.5.9	<p>Are the test cases and procedures sufficient to cover all the relevant requirements (including environmental qualification test requirements)? That is, do the traceability matrices provide clear association between test cases and requirements?</p> <p>Note: This is also applicable for Previously Developed Hardware. Refer to DO-254, section 6.3.2.</p>	<ul style="list-style-type: none"> • 6.2.1(1,2,3)
3.5.10	Does each test case have procedures for test set-up (include the test environment), test execution, and pass-fail criteria?	<ul style="list-style-type: none"> • 6.2.1(1,3)
3.5.11	If test cases are run on a simulator or emulator (for DO-254 compliance), has the simulator or emulator eliminated any of the test steps? If so, has the simulator or emulator been assessed for tool qualification per section 11.4 of DO-254?	<ul style="list-style-type: none"> • 6.2.1(1,3)
3.5.12	Are there sufficient tests to provide adequate verification coverage of the hardware?	<ul style="list-style-type: none"> • 6.2.1(1,2,3)
3.6	Review checklists for test cases, procedures, and results, considering the following questions:	
3.6.1	Are the checklists sufficient to determine that the requirements-based test cases, procedures, and results meet verification objectives?	<ul style="list-style-type: none"> • 6.2.1(1,3)
3.6.2	<p>Do the checklists specify:</p> <ul style="list-style-type: none"> - who performed the review? - what was reviewed (with revision data)? - when it was reviewed? - what was found? - references to corrective actions, where necessary? 	<ul style="list-style-type: none"> • 6.2.1(1,3,4)

Item #	SOI #3 Evaluation Activity/Question	Related DO-254 objective(s)
3.6.3	<p>Will the test case, procedures, and test results checklists reveal whether the results of the test cases that are counted for credit are observable? That is, does the test procedure require that the test results are collected with standard instrumentation and not inferred by observing the high-level system performance? Is this an item on the verification checklists?</p> <p>Note: This ensures that the test cases/procedures for a named signal that can be recorded and repeated.</p>	<ul style="list-style-type: none"> • 6.2.1(1)
3.6.4	<p>Will the procedure checklists reveal test cases that violate project standards?</p>	<ul style="list-style-type: none"> • 6.2.1(1,3)
3.6.5	<p>Will the procedures checklists reveal test cases that are not expected to achieve coverage of every functional element as described in DO-254 Appendix B section 3.3.1?</p>	<ul style="list-style-type: none"> • 6.2.1(1,3)
3.6.6	<p>Do the test case, procedures, and results checklists require evaluation of specified tolerances?</p>	<ul style="list-style-type: none"> • 6.2.1(1,3)
3.6.7	<p>Have the test case, procedures, and results checklists been reviewed?</p>	<ul style="list-style-type: none"> • 6.2.1(1) • 8.1(2)
3.7	<p>Review and assess the test results. Consider the following questions:</p>	
3.7.1	<p>Are the test result files clearly linked to the test procedures and detailed design (i.e., does configuration control and traceability exist)?</p>	<ul style="list-style-type: none"> • 6.2.1(2) • 7.1(1,2,3)
3.7.2	<p>Is each test result clearly linked to a test case?</p>	<ul style="list-style-type: none"> • 6.2.1(2)
3.7.3	<p>Are failed test cases obvious from the test results?</p>	<ul style="list-style-type: none"> • 6.2.1(3)
3.7.4	<p>Do the test results indicate whether each procedure passed or failed and the final pass/fail results?</p>	<ul style="list-style-type: none"> • 6.2.1(3)
3.7.5	<p>Do the test results adhere to the relevant plans, standards, and procedures?</p>	<ul style="list-style-type: none"> • 6.2.1(1,3) • 8.1(2)
3.7.6	<p>Witness at least one requirements-based test and consider the following questions:</p> <ul style="list-style-type: none"> • Are the tests repeatable? • Are the tests complete? • Do the results agree with what was included in the test results? • Does the test verify the requirement? 	<ul style="list-style-type: none"> • 6.2.1(1,2,3) • 8.1(2)
3.7.7	<p>Have all discrepancies between expected results and actual results been documented, explained or fed back to the appropriate process for resolution?</p>	<ul style="list-style-type: none"> • 6.2.1(1,3,4)

Item #	SOI #3 Evaluation Activity/Question	Related DO-254 objective(s)
3.7.8	Does traceability exist between test results, test cases and requirements	<ul style="list-style-type: none"> • 6.2.1(2)
3.7.9	Have the hardware requirements been tested/verified?	<ul style="list-style-type: none"> • 6.2.1(1,2,3)
3.7.10	Does the reviewed data support the process defined in the Hardware Validation/Verification Plan?	<ul style="list-style-type: none"> • 8.1(2)
3.7.11	Have the test results been subjected to appropriate configuration control?	<ul style="list-style-type: none"> • 7.1 (1,2,3)
3.8	Review and assess failure explanations and rework. Consider the following questions:	
3.8.1	Is there an acceptable rationale for deviations from expected results, standards, or plans?	<ul style="list-style-type: none"> • 6.2.1(1,3) • 8.1(2)
3.8.2	Are explanations for the failed test cases documented, understandable, and linked to relevant problem reports?	<ul style="list-style-type: none"> • 6.2.1(1,3,4)
3.8.3	Are explanations for detailed design or test rework suitable to address the failure?	<ul style="list-style-type: none"> • 6.2.1(1,3,4)
3.8.4	Have test cases been re-executed in compliance with plans for regression testing?	<ul style="list-style-type: none"> • 6.2.1(1,3,4)
3.9	Review and assess verification coverage achievement, considering the following questions:	
3.9.1	Is 100% HDL coverage achieved through requirements-based testing? If 100% coverage is not achieved through requirements-based testing, is there an explanation detailing which parts of the code were not executed and why? Are explanations for drops in coverage sufficiently detailed and acceptable?	<ul style="list-style-type: none"> • 6.2.1(1)
3.10	Review the integration process data to determine compliance to DO-254.	
3.10.1	How is each objective for the board level integration (including HW/SW integration) and verification process met?	<ul style="list-style-type: none"> • 6.2.1(1)
3.10.2	Does the integration test process comply with the plans?	<ul style="list-style-type: none"> • 6.2.1(1)
3.10.3	Are there any hardware verification objectives met by software (DO-178B) verification activities? If so, are they identified and documented?	<ul style="list-style-type: none"> • 6.2.1(1)

Item #	SOI #3 Evaluation Activity/Question	Related DO-254 objective(s)
3.11	Review the Problem Reports and changes to hardware life cycle data for impact on hardware design.	
3.11.1	Is the applicant documenting problems as described in their plans (e.g., problem reports)?	<ul style="list-style-type: none"> • 6.2.1(4) • 8.1(2)
3.11.2	Is there a problem reporting process in place? Is there a change control process? Is the applicant following the process?	<ul style="list-style-type: none"> • 6.2.1(4) • 7.1(1,2,3)
3.11.3	Does the problem report adequately describe the deficiency or anomalous behavior and the proposed change(s)?	<ul style="list-style-type: none"> • 6.2.1(4)
3.11.4	Are all effected hardware module(s) identified?	<ul style="list-style-type: none"> • 7.1(1,2,3)
3.11.5	Was the configuration updated to reflect the new version(s)?	<ul style="list-style-type: none"> • 7.1(1,2,3)
3.11.6	Does the description in the problem report adequately describe the change made?	<ul style="list-style-type: none"> • 6.2.1(4)
3.11.7	Was the correct form for problem reports used?	<ul style="list-style-type: none"> • 8.1(2)
3.11.8	How was change authorization confirmed?	<ul style="list-style-type: none"> • 8.1(2)
3.11.9	Was the change documented in the prologue header?	<ul style="list-style-type: none"> • 8.1(2)
3.11.10	If the change affected the hardware design was the design data updated or a change applied to the baseline?	<ul style="list-style-type: none"> • 6.2.1(4) • 7.1(1,2,3) • 8.1(2)
3.11.11	If the change effected the requirements, were the requirements updated or a change applied to the baseline?	<ul style="list-style-type: none"> • 6.2.1(4) • 7.1(1,2,3) • 8.1(2)
3.11.12	Were retest, regression analysis, and safety affects addressed in the change process?	<ul style="list-style-type: none"> • 6.2.1(4) • 7.1(3)
3.12	Review the Archival, Retrieval, and Release Procedures.	
3.12.1	Was the product protected from unauthorized changes?	<ul style="list-style-type: none"> • 7.1(3)
3.12.2	Does the storage medium minimize risk of deterioration and regeneration of errors?	<ul style="list-style-type: none"> • 7.1(2)
3.12.3	Are copies stored in physically separate archives for disaster recovery?	<ul style="list-style-type: none"> • 7.1(2)
3.12.4	Are there provisions to make and verify error free copies, including executable document name, version, and date; paragraph numbers; requirements identification; and results?	<ul style="list-style-type: none"> • 7.1(2)

Item #	SOI #3 Evaluation Activity/Question	Related DO-254 objective(s)
3.13	If tool qualification is required for verification tools, review tool qualification data, considering the following questions:	
3.13.1	Do the plans state which tools are being qualified and the rationale for qualification? Note: This might be in the Plan for Hardware Aspects of Certification or a separate tool qualification plan for verification tools.	<ul style="list-style-type: none"> • 6.2.1(1)
3.13.2	Are the specific verification tool requirements documented?	<ul style="list-style-type: none"> • 6.2.1(1)
3.13.3	If a qualified tool is used for verification coverage, does the tool qualification data address whether the tool needs to instrument the HDL (if applicable) to perform the analysis? If the tool does need to instrument the HDL, has the effect of the instrumentation on the code been assessed?	<ul style="list-style-type: none"> • 6.2.1(1)
3.13.4	Is the tool qualification analysis sufficient to discover errors in the verification tool and limitations of the tool's functions?	<ul style="list-style-type: none"> • 6.2.1(1,4)
3.13.5	Does the tool qualification data address how tool deficiencies that are found while the verification tools are being used in a certification project should be handled?	<ul style="list-style-type: none"> • 6.2.1(4)
3.13.6	Does the tool qualification data detail how changes to the verification tool will be evaluated and controlled?	<ul style="list-style-type: none"> • 7.1(3)
3.13.7	Are procedures for using each verification tool documented?	<ul style="list-style-type: none"> • 6.2.1(1)
3.14	Review Level A & B Verification	
3.14.1	Have the independence requirements for verification been satisfied (see Appendix B of DO-254)?	<ul style="list-style-type: none"> • 6.2.1(1)
3.14.2	Is the functional failure path analysis (FFPA) complete (see Appendix B of DO-254)?	<ul style="list-style-type: none"> • 6.2.1(1)
3.14.3	Are the functional failure paths identified (see Appendix B of DO-254)?	<ul style="list-style-type: none"> • 6.2.1(1)
3.14.4	Is the additional assurance method appropriate and complete (see Appendix B of DO-254)?	<ul style="list-style-type: none"> • 6.2.1(1)

3.4 ACTIVITIES FOR STAGE OF INVOLVEMENT #4 – FINAL REVIEW

Purpose

- ⊖ Determine if final compliance to all of the DO-254 objectives has been achieved and all open items addressed/dispositioned.
- ⊖ Assess the Hardware Configuration Management Records (including those for the hardware life cycle environment), Hardware Accomplishment Summary, and any other documents not previously reviewed.

When to Perform

When the hardware life cycle is completed, and the following items have been completed by the applicant (or when deemed necessary):

- ⊖ Hardware conformity review has been performed.
- ⊖ Hardware Configuration Management Records have been reviewed and are correct.
- ⊖ Formal signature process has been completed.

Data to Review Prior to the Review

Reports from SOI #1, SOI #2, and/or SOI #3; open items from SOI #1, SOI #2, and/or SOI #3; all plans; Hardware Accomplishment Summary; and Hardware Configuration Management Records.

Data to Review at the Review

Hardware Configuration Management Records; Problem Reports; Hardware Accomplishment Summary; Designees’ findings/observations from pre-review activities; and any data that had issues in previous reviews.

Number of Days

1-3 days

Note 1: If SOI #1, SOI #2, and SOI #3 have been performed, SOI #4 may only be an assessment of whether or not outstanding issues have been resolved (in this case the review might take only 1 day).

Note 2: If SOI #1, SOI #2, and SOI #3 were not performed, this review could take much longer.

**Evaluation Activities
and Questions**

During SOI #4 the Hardware Accomplishment Summary and Hardware Configuration Management Records are evaluated. Additionally, open items from previous reviews are evaluated to ensure that all of the DO-254 objectives and project issues are addressed. Table 8 provides typical activities and questions for SOI #4.

Instructions

- ⊖ There are ten evaluation activities/questions for Stage of Involvement #4 - Final Review.

- ⊖ Review the questions for each activity in relationship to its corresponding DO-254 objective and level.

Table 8. SOI #4 Evaluation Activities

Item #	SOI #4 Evaluation Activity/Question	Related DO-254 objective(s)
4.1	Were activities performed from SOI #1, SOI #2, or SOI #3 that were not previously completed or that were not found satisfactory and required changes completed?	<ul style="list-style-type: none"> • All
4.2	Has the Hardware Accomplishment Summary been reviewed (e.g., includes the required information and addresses hardware identification, change history, hardware status (unresolved problems and limitations) and compliance statement)? See section 10.9 of DO-254.	<ul style="list-style-type: none"> • 8.1(1,2,3)
4.3	Do the Hardware Configuration Management Records adequately identify all elements of the hardware life cycle environment necessary for hardware regeneration, reverification, or hardware modification?	<ul style="list-style-type: none"> • 7.1(1,2,3)
4.4	Do the Hardware Configuration Management Records adequately identify the hardware item and all subassemblies and subcomponents?	<ul style="list-style-type: none"> • 7.1(1,2,3)
4.5	Are all required hardware life cycle data under appropriate configuration control?	<ul style="list-style-type: none"> • 7.1(1,2,3)
4.6	<p>In assessing problem reports, determine if the following have been properly analyzed and addressed:</p> <ul style="list-style-type: none"> • Are there any open problem reports that affect safety? Is there a person or organization whose responsibilities ensure that any safety implications of leaving these problem reports open have been properly addressed? • Are there any open problem reports that affect operations? • Are the open problem reports categorized correctly (e.g., “impacts safety” vs. “product improvement”)? • Have problem reports been adequately analyzed? 	<ul style="list-style-type: none"> • 8.1(1,2,3)
4.7	Complete the Summary of Compliances/Findings/Observations table for all objectives for the appropriate hardware level.	<ul style="list-style-type: none"> • 8.1(1,2,3)
4.8	Does the system still satisfy the safety assessment objectives? Ensure that the planned safety objectives were actually addressed in the project implementation. Is there a person or organization whose responsibilities ensure that the system design addresses all the safety assessment objectives?	<ul style="list-style-type: none"> • 8.1(1,2,3)
4.9	Ensure that all applicable DO-254 objectives have been satisfied.	<ul style="list-style-type: none"> • 8.1(1,2,3)
4.10	Was the hardware conformity review performed on the “as-built” system? Do the Hardware Configuration Management Records capture the “as-built” information? (See section 10.3.2.2.1 of DO-254.)	<ul style="list-style-type: none"> • 7.1(1,2,3) • 8.1(1,2,3)

PART 4 - SUMMARIZING COMPLIANCES, FINDINGS, AND OBSERVATIONS FOR EACH DO-254 OBJECTIVE

This section provides a way to tie the applicant's activities and compliance with the objectives of DO-254 and to document any findings and observations. For each objective, the review team evaluates what evidence exists to verify compliance. The "Summary of Compliances/Findings/Observations" form is included on the following pages. This form flags any issues found during a hardware review that may be considered certification issues. If the objective is not met, the reason for non-compliance should be stated in the form. This form provides a summary and tracking mechanism for discussions with the applicant.

While carrying out the activities/questions in Part 3 of the Job Aid, findings and observations are typically made. Findings should be mapped against the objectives of DO-254 using the Summary of Compliances/Findings/Observations form in this section. Observations may also be recorded in these tables, if desired; however, it should be clearly stated which are observations and which are findings. Additionally, the compliances to DO-254 objectives that were evaluated should be documented.

The Summary of Compliances/Findings/Observations form has four columns. The first column summarizes the DO-254 objectives. The second column provides reference to a DO-254 section. The third column provides a place to record the Compliances/Findings/Observations found during a review. The last column provides a tie back to the Job Aid tables in Part 3 of this Job Aid.

Completion of these tables should be performed during and/or after the hardware review and should be included as part of the review report. All applicable DO-254 objectives should be assessed for compliance. Any actions and issues should also be noted during the review, but will likely be summarized in a separate table, since they may not tie to specific DO-254 objectives.

Note: This section provides one way to summarize review results. Appendix A provides an alternate approach that may be effective as well. In both cases, it is important to evaluate all applicable DO-254 objectives and to document where compliances have been found and where findings and/or observations exist.

Objective Summary	DO-254 section reference	Summary of Compliances/ Findings/Observations	Job Aid Ref.
Planning			
The hardware design life cycle processes are defined.	4.1(1)		1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 2.1, 3.1
The hardware development and verification environments are selected or defined.	4.1(2)		1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 2.1, 2.2, 3.1
The means of compliance of the hardware design assurance objectives, including strategies identified using guidance in Section 2.3.4, are proposed to the Certification Authority.	4.1(3)		1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 2.1, 3.1
Standards are selected and defined.	4.1(4)		1.1, 1.2, 1.3, 1.4, 1.5, 1.8, 2.1, 3.1
Requirements Capture			
Requirements are identified, defined and documented.	5.1.1(1)		1.4, 2.2, 3.1
Derived requirements produced are fed back to the appropriate process.	5.1.1(2)		1.4, 2.2, 3.1

Objective Summary	DO-254 section reference	Summary of Compliances/ Findings/Observations	Job Aid Ref.
Requirement omissions and errors are provided to the appropriate process for resolution.	5.1.1(3)		1.4, 2.2, 3.1
Conceptual Design			
The hardware item conceptual design is developed consistent with its requirements.	5.2.1(1)		1.4, 2.2, 2.3, 3.1
Derived requirements produced are fed back to the requirements capture or other appropriate processes.	5.2.1(2)		1.4, 2.3, 3.1
Requirement omissions and errors are provided to the appropriate process for resolution.	5.2.1(3)		1.4, 2.3, 3.1
Detailed Design			
Detailed design is developed from the hardware item requirements and conceptual design data.	5.3.1(1)		1.4, 2.2, 2.4, 3.1
Derived requirements are fed back to the conceptual design process or other appropriate processes.	5.3.1(2)		1.4, 2.4, 3.1
Requirement omissions and errors are provided to the appropriate process for resolution	5.3.1(3)		1.4, 2.4, 3.1
Implementation			

Objective Summary	DO-254 section reference	Summary of Compliances/ Findings/Observations	Job Aid Ref.
A hardware item is produced which implements the hardware detailed design using the representative manufacturing processes.	5.4.1(1)		1.4, 2.5, 3.1
The hardware item implementation, assembly and installation data is complete.	5.4.1(2)		1.4, 2.5, 3.1
Derived requirements are fed back to the conceptual design process or other appropriate processes.	5.4.1(3)		1.4, 2.5, 3.1
Requirements omissions and errors are provided to the appropriate processes for resolution.	5.4.1(4)		1.4, 2.5
Production Transition			
A baseline is established that includes all design and manufacturing data needed to support the consistent replication of the hardware item.	5.5.1(1)		1.4, 2.6, 3.1
Manufacturing requirements related to safety are identified and documented and manufacturing controls are established.	5.5.1(2)		1.4, 2.6, 3.1

Objective Summary	DO-254 section reference	Summary of Compliances/ Findings/Observations	Job Aid Ref.
Derived requirements are fed back to the implementation process or other appropriate processes.	5.5.1(3)		1.4, 2.6, 3.1
Errors and omissions are provided to the appropriate processes for resolution.	5.5.1(4)		2.6, 3.1
Validation			
Derived hardware requirements against which the hardware item is to be verified are correct and complete.	6.1.1(1)		1.7, 2.2, 3.3
Derived requirements are evaluated for impact on safety.	6.1.1(2)		1.7, 3.3
Omissions and errors are fed back to the appropriate processes for resolution.	6.1.1(3)		1.7, 3.3
Verification			
Evidence is provided that the hardware implementation meets the requirements.	6.2.1(1)		1.7, 2.2, 3.4, 3.5, 3.6, 3.7, 3.9, 3.10, 3.13, 3.14
Traceability is established between hardware requirements, the implementation, and the verification procedures and results.	6.2.1(2)		1.7, 2.2, 2.3, 2.4, 2.5, 3.4, 3.5, 3.7, 3.8

Objective Summary	DO-254 section reference	Summary of Compliances/ Findings/Observations	Job Aid Ref.
Acceptance test criteria are identified, can be implemented and are consistent with the hardware design assurance levels of the hardware functions.	6.2.1(3)		1.7, 2.2, 3.5, 3.6, 3.7, 3.8
Omissions and errors are fed back to the appropriate processes for resolution.	6.2.1(4)		3.6, 3.7, 3.8, 3.11, 3.13
Configuration Management			
Configuration items are uniquely identified and documented.	7.1(1)		1.1, 1.3, 1.5, 2.2, 2.3, 3.5, 3.7, 3.11, 4.0
Consistent and accurate replication of configuration items is ensured.	7.1(2)		1.1, 1.3, 1.5, 2.2, 2.3, 3.5, 3.7, 3.11, 3.12, 4.0
A controlled method of identifying and tracking modification to configuration items is provided.	7.1(3)		1.1, 1.3, 1.5, 1.6, 2.2, 2.3, 3.5, 3.7, 3.11, 3.12, 3.13, 4.0
Process Assurance			
Life cycle processes comply with the approved plans.	8.1(1)		1.6, 2.2, 3.2, 4.0
Hardware design life cycle data produced complies with the approved plans.	8.1(2)		1.6, 2.2, 3.2, 3.6, 3.7, 3.8, 3.11, 4.0
The hardware item used for conformance assessment is built to comply with the associated life cycle data.	8.1(3)		1.6, 4.0

Note: The material contained in Table 9.regarding DO-254 objectives is copyrighted by RTCA, Inc. and used with permission. DO-254, along with all RTCA, Inc. documents, may be purchased directly from RTCA, Inc. To order a copy of DO-254 or any other RTCA, Inc. documents, please contact:

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**APPENDIX A – ALTERNATE APPROACH FOR RECORDING
COMPLIANCES/FINDINGS/OBSERVATION**

Table A1. Alternate Method for Documenting Review Compliances/Findings/Observations

Item #	Doc	DO-254 Obj.	C/F/O	Description	Applicant Response	Status
Note 1	Note 2	Note 3	Note 4	Note 5	Note 6	Note 7

- Note 1: Number the item for future reference.
- Note 2: Include document or data that the finding or observation is made against.
- Note 3: Include the applicable DO-254 objective(s)
- Note 4: Classify the item as a finding (F), observation (O), or compliance (C). Issues (I), actions (A), and notes (N) might also be included in this format.
- Note 5: Describe the review finding or observation – be specific
- Note 6: Allow space for the applicant to respond to each item of the review report. This will typically include their strategy for dealing with the finding or observation.
- Note 7: Document status of items, as the project matures. The goal is for all findings to be closed or properly dispositioned.

APPENDIX B – DO-254 OBJECTIVES SUMMARY**Table B1. Hardware Planning Process**

	Objective		Hardware Life Cycle Data		Control Category By HW Assurance Level			
	Description	Ref.	Description	Ref.	A	B	C	D
1	The hardware design life cycle processes are defined.	4.1(1)	Plan for Hardware Aspects of Certification	10.1.1	HC1	HC1	HC1	HC1
2	The hardware development and verification environments are selected or defined.	4.1(3)	Hardware Design Plan	10.1.2	HC2	HC2	HC2	NA
3	The means of compliance of the hardware design assurance objectives, including strategies identified using guidance in RTCA/DO-254 Section 2.3.4, are proposed to the certification authority.	4.1(4)	Hardware Validation Plan (Note 3 & 4)	10.1.3	HC2	HC2	HC2	NA
			Hardware Verification Plan	10.1.4	HC2	HC2	HC2	HC2
			Hardware Configuration Plan	10.1.5	HC1	HC1	HC2	HC2
			Hardware Process Assurance Plan (except objective. 4.1.(3))	10.1.6	HC2	HC2	NA	NA
4	Standards are selected and defined.	4.1(2)	Requirements Standards (Note 3)	10.2.1	HC2	HC2	NA	NA
			Hardware Design Standards (Note 3)	10.2.2	HC2	HC2	HC2	NA
			Validation and Verification Standards (Note 3)	10.2.3	HC2	HC2	NA	NA
			Hardware Archive Standards (Note 3)	10.2.4	HC2	HC2	NA	NA

Relevant notes from RTCA/DO-254 Appendix A, Table A-1:

Note 3. If this data is used for certification, then its availability is shown in the table. This data is not always used for certification and may not be required.

Note 4. This can be accomplished informally through the certification liaison process for Levels C and D. Documentation can be in the form of meeting minutes and or presentation material.

Table B2. Hardware Design Process

Objective		Hardware Life Cycle Data		Control Category By HW Assurance Level				
	Description	Ref.	Description	Ref.	A	B	C	D
	Requirements Capture							
1	Requirements are identified, defined and documented.	5.1.1(1)	Hardware Requirements	10.3.1	HC1	HC1	HC1	HC1
2	Derived requirements produced are fed back to the appropriate process.	5.1.1(2)						
3	Requirement omissions and errors are provided to the appropriate process for resolution.	5.1.1(3)	Problem Reports	10.6	HC2	HC2	HC2	HC2
	Conceptual Design							
4	The hardware item conceptual design is developed consistent with its requirements.	5.2.1(1)	Conceptual Design Data (Note 3)	10.3.2.1	HC2	HC2	NA	NA
5	Derived requirements produced are fed back to the requirements capture or other appropriate processes.	5.2.1(2)	Hardware Requirements	10.3.1	HC1	HC1	HC1	HC1
7	Requirement omissions and errors are provided to the appropriate process for resolution.	5.2.1(3)	Problem Reports	10.6	HC2	HC2	HC2	HC2
	Detailed Design							
8	Detailed design is developed from the hardware item requirements and conceptual design data.	5.3.1(1)	Detailed Design Data	10.3.2.2	Note5	Note5	Note5	Note5
			Top-Level Drawing	10.3.2.2.1	HC1	HC1	HC1	HC1
			Assembly Drawing	10.3.2.2.2	HC1	HC1	HC1	HC1
			HW/SW Interface Data	10.3.2.2.4	HC1	HC1	HC1	HC1

9	Derived requirements are fed back to the conceptual design process or other appropriate processes.	5.3.1(2)	Hardware Requirements	10.3.1	HC1	HC1	HC1	HC1
10	Requirement omissions and errors are provided to the appropriate process for resolution.	5.3.1(3)	Problem Reports	10.6	HC2	HC2	HC2	HC2
Implementation								
11	A hardware item is produced which implements the hardware detailed design using the representative manufacturing processes.	5.4.1(1)	Detailed Design Data	10.3.2.2	Note5	Note5	Note5	Note5
			Top-Level Drawing	10.3.2.2.1	HC1	HC1	HC1	HC1
12	The hardware item implementation, assembly and installation data is complete.	5.4.1(2)	Assembly Drawing	10.3.2.2.2	HC1	HC1	HC1	HC1
			Installation Control Drawings	10.3.2.2.3	HC1	HC1	HC1	HC1
13	Derived requirements are fed back to the conceptual design process or other appropriate processes.	5.4.1(3)	Hardware Requirements	10.3.1	HC1	HC1	HC1	HC1
14	Requirement omissions and errors are provided to the appropriate processes for resolution.	5.4.1(4)	Problem Reports	10.6	HC2	HC2	HC2	HC2
Production Transition								
15	A baseline is established that includes all design and manufacturing data needed to support the consistent replication of the hardware item.	5.5.1(1)	Hardware Requirements	10.3.1	HC1	HC1	HC1	HC1
			Top-Level Drawing	10.3.2.2.1	HC1	HC1	HC1	HC1
			Assembly Drawing	10.3.2.2.2	HC1	HC1	HC1	HC1
			Installation Control Drawings	10.3.2.2.3	HC1	HC1	HC1	HC1
			Hardware Configuration Management Records	10.7	HC2	HC2	HC2	HC2

16	Manufacturing requirements related to safety are identified and documented and manufacturing controls are established.	5.5.1(2)	Hardware Requirements	10.3.1	HC1	HC1	HC1	HC1
17	Derived requirements are fed back to the implementation process or other appropriate processes.	5.5.1(3)	Hardware Acceptance Test Criteria	10.5	HC2	HC2	HC2	HC2
18	Errors and omissions are provided to the appropriate processes for resolution.	5.5.1(4)	Problem Reports	10.6	HC2	HC2	HC2	HC2

Relevant notes from RTCA/DO-254 Appendix A, Table A-1:

Note 3. If this data is used for certification, then its availability is shown in the table. This data is not always used for certification and may not be required.

Note 5. If the applicant references this data item in submitted data items, it should be available.

Table B3. Validation and Verification Processes

Objective		Hardware Life Cycle Data		Control Category By HW Assurance Level				
Description	Ref.	Description	Ref.	A	B	C	D	
Validation								
1	Derived hardware requirements against which the hardware item is to be verified are correct and complete.	6.1.1(1)	Hardware Validation Plan	10.1.3	HC2	HC2	HC2	HC2
2	Derived requirements are evaluated for impact on safety.	6.1.1(2)	Hardware Traceability Data	10.4.1	HC2	HC2	HC2 Note6	HC2 Note6
			Hardware Review and Analysis Procedures (Note 3)	10.4.2	HC1	HC1	NA	NA
			Hardware Review and Analysis Results (Note 3)	10.4.3	HC2	HC2	HC2	HC2
			Hardware Test Procedures (Note 3)	10.4.4	HC1	HC1	HC2	HC2 Note7
			Hardware Test Results (Note 3)	10.4.5	HC1	HC1	HC2	HC2 Note7
3	Omissions and errors are fed back to the appropriate processes for resolution.	6.1.1(3)	Problem Reports	10.6	HC2	HC2	HC2	HC2

	Verification							
4	Evidence is provided that the hardware implementation meets the requirements.	6.2.1(1)	Hardware Verification Plan	10.1.4	HC2	HC2	HC2	HC2
5	Traceability is established between hardware requirements, the implementation, and the verification procedures and results.	6.2.1(2)	Hardware Traceability Data	10.4.1	HC2	HC2	HC2 Note6	HC2 Note6
			Hardware Review and Analysis Procedures (Note 3)	10.4.2	HC1	HC1	NA	NA
			Hardware Review and Analysis Results (Note 3)	10.4.3	HC2	HC2	HC2	HC2
			Hardware Test Procedures (Note 3)	10.4.4	HC1	HC1	HC2	HC2 Note7
			Hardware Test Results (Note 3)	10.4.5	HC1	HC1	HC2	HC2 Note7
6	Acceptance test criteria are identified, can be implemented and are consistent with the hardware design assurance levels of the hardware functions.	6.2.1(3)	Hardware Acceptance Test Criteria	10.5	HC2	HC2	HC2	HC2
7	Omissions and errors are fed back to the appropriate processes for resolution.	6.1.1(3)	Problem Reports	10.6	HC2	HC2	HC2	HC2
		6.2.1(4)	Hardware Configuration Management Records	10.7	HC2	HC2	HC2	HC2

Relevant notes from RTCA/DO-254 Appendix A, Table A-1:

Note 3. If this data is used for certification, then its availability is shown in the table. This data is not always used for certification and may not be required.

Note 6. Only the traceability data from requirements to test is needed.

Note 7. Test coverage of derived or lower hierarchical requirements is not needed.

Table B4. Configuration Management and Process Assurance Processes

Objective		Hardware Life Cycle Data		Control Category By HW Assurance Level				
Description	Ref.	Description	Ref.	A	B	C	D	
Configuration Management								
1	Configuration items are uniquely identified and documented.	7.1(1)	Hardware Configuration Management Records	10.7	HC2	HC2	HC2	HC2
			Hardware Archive Standards (Note 3)	10.2.4	HC2	HC2	NA	NA
2	Consistent and accurate replication of configuration items is ensured.	7.1(2)	Hardware Configuration Management Records	10.7	HC2	HC2	HC2	HC2
			Hardware Process Assurance Records	10.8	HC2	HC2	HC2	NA
			Hardware Archive Standards (Note 3)	10.2.4	HC2	HC2	NA	NA
3	A controlled method of identifying and tracking modification to configuration items is provided.	7.1(3)	Hardware Configuration Plan	10.1.5	HC1	HC1	HC2	HC2
			Hardware Configuration Management Records	10.7	HC2	HC2	HC2	HC2
			Problem Reports	10.6	HC2	HC2	HC2	HC2
Process Assurance								
4	Life cycle processes comply with the approved plans.	8.1(1)	Hardware Process Assurance Plan	10.1.6	HC2	HC2	NA	NA
5	Hardware design life cycle data produced complies with the approved plans.	8.1(2)	Hardware Process Assurance Records	10.8	HC2	HC2	HC2	NA
			Hardware Accomplishment Summary	10.9	HC1	HC1	HC1	HC1
6	The hardware item used for conformance assessment is built to comply with the associated life cycle data.	8.1(3)						

Relevant notes from RTCA/DO-254 Appendix A, Table A-1:

Note 3. If this data is used for certification, then its availability is shown in the table. This data is not always used for certification and may not be required.

Note: The material contained in Tables B1 through B4 in this Job Aid regarding DO-254 objectives and notes is copyrighted by RTCA, Inc. and used with permission. DO-254, along with all RTCA, Inc. documents, may be purchased directly from RTCA, Inc. To order a copy of DO-254 or any other RTCA, Inc. documents, please contact:

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APPENDIX C – FREQUENTLY ASKED QUESTIONS

Q1: Part 1, Overview of the Airborne electronic Hardware Review, states that the Job Aid “should not be used as a checklist.” What does this mean? If it isn’t a checklist, how should the Job Aid be used?

A1: This Job Aid identifies questions that may need to be addressed in order to evaluate compliance. However, the questions do not represent specific audit tasks to accomplish. They are not a list of things to do. The review team must decide what activities to perform and which questions are applicable to those activities. You can think of these questions as the requirements for a review, and the review team has to generate the “review procedures” that will verify that requirements are met. For example, one common review technique is to perform a requirements trace. There is no question that asks about “performing a requirements trace” but there are a number of questions that can be addressed while doing a trace. As another example, item 1.1.3 in Table 5 states, “Do the plans and standards address the content as specified in DO-254 section 10.” This is no small task. It requires a review of each of the plans against the section 10 content list. But there is more to a plan than just section 10 content. The review team could create a checklist for each plan and include in it all section 10 content as well as review items that will address the other compliance aspects of the documents, such that when the document reviews are done, there is evidence of compliance for each applicable question.

Do not expect to answer each and every question in Tables 5, 6, 7 and 8 of this Job Aid during a review. Plan ahead. Use only those questions that are appropriate for the review you are performing. Create additional questions, if there are new and novel concerns that are not adequately being covered by this Job Aid. This Job Aid is meant to be used as a tool, but as a flexible tool that requires judgment about how it is applied.

Q2: The questions contained in the Tables 5, 6, 7 and 8 seem very much targeted at a review of Complex Airborne Electronic Hardware. Can this Job Aid be used to assist in the review of Simple Airborne Electronic Hardware?

A2: Yes. That is inherent in the title of this Job Aid, which is “Conducting Airborne Electronic Hardware Reviews”. Airborne hardware includes both complex and simple hardware. However, there are several issues that the user must be aware of in order to use this Job Aid effectively when performing an audit on a Simple Airborne Electronic Hardware.

FAA AC 20-20-152, “RTCA, INC., DOCUMENT RTCA/DO-254, DESIGN ASSURANCE GUIDANCE FOR AIRBORNE ELECTRONIC HARDWARE”, does not invoke RTCA/DO-254 as an acceptable means of compliance for Simple Airborne Electronic Hardware. The AC specifically states that it is invoking DO-254 for

“**complex** custom micro-coded components”, such as application specific integrated circuits (ASIC), programmable logic devices (PLD), field programmable gate arrays (FPGA), and similar electronic components used in the design of aircraft systems and equipment. Therefore, while AC 20-152 does not exclude the use of DO-254 for Simple Airborne Electronic Hardware, it does not specifically document it as an acceptable means of compliance for that type of hardware.

The main difference between Complex Airborne Electronic Hardware and Simple Airborne Electronic Hardware is that Simple hardware is not developed using a rigorous design assurance process. Rather, exhaustive testing of the end item product is the method used to ensure that a Simple hardware device contains no errors or unacceptable behavior, and that systems in which the device is installed will meet the applicable regulatory requirements. Therefore, many of the objectives (and the related questions about how to assess compliance to those objectives) are not relevant to Simple Airborne Electronic Hardware.

However, there are certainly processes contained in DO-254 that *are* relevant to both Simple and Complex Airborne Electronic Hardware devices. Specifically, all or parts of the following sections of DO-254 are relevant to Simple Airborne Electronic Hardware.

- 2.0 SYSTEM ASPECTS OF HARDWARE DESIGN ASSURANCE
- 7.0 CONFIGURATION MANAGEMENT PROCESS
- 8.0 PROCESS ASSURANCE
- 9.0 CERTIFICATION LIASON PROCESS
- 10.0 HARDWARE DESIGN LIFE CYCLE DATA

This Job Aid does not attempt to specify which DO-254 objectives and their related questions in Tables 5, 6, 7 and 8 are relevant to Simple devices. Judgment should be used in the application of these questions and related DO-254 objectives when attempting to determine compliance or non-compliance for Simple Airborne Electronic Hardware.

Please refer to Order 8110.CEH* for more information regarding Simple Airborne Electronic Hardware.

* Order 8110.CEH will cover aspects of both Complex and Simple Custom Micro-Coded Devices, also referred to as CEH (Complex Electronic Hardware devices) and SEH (Simple Electronic Hardware devices). This Order has not been published at the time of initial publication of this Job Aid, and therefore cannot be referred to by a specific Order number or title.

Q3: Is compliance to DO-254 related only to the objectives compiled in Appendix B of this Job Aid?

A3: No. This Job Aid provides a means of determining compliance to DO-254 by referencing the objectives of DO-254. Each reference to an objective is merely a convenient way to identify the guidance that the objective summarizes. This is not to suggest that the objectives are more important than the guidance. Compliance to DO-254 means compliance to the guidance itself and not solely to the objectives.

Q4: If the FAA is in charge of the review, does the Hardware Review Team consist only of FAA personnel?

A4: Not necessarily. Each review, and the team that performs the review, will be unique. The FAA should take advantage of any expertise that is available. For example, consultant DERs that are working with the avionics supplier or applicant may be a member of the Review Team. They should be very knowledgeable about the program, documentation and possible problem areas and can therefore make suggestions to the team about where to concentrate their efforts.

Additionally, non-U.S. Certification Authority personnel such as from EASA or Transport Canada or other authorities may be present, in the case of a joint review. The Team Leader should understand the motivations and needs from each prospective team member, and assign tasks accordingly. For example, a non-U.S. Certification Authority representative is present and is concerned about a configuration management issue, perhaps based on previous experience with this hardware supplier. The Review Team Leader should understand this concern and assign the representative to look into this area. The Team Leader is responsible for completing the review activities that is needed by the FAA, but also should be mindful of any non-U.S. Certification Authority needs as well and attempt to accommodate them (e.g., evaluating compliance to a non-U.S. Certification Authority Issue Paper), when the non-U.S. representative is a team member. Otherwise, the various Certification Authority personnel may end up working at cross-purposes to each other. Another possibility is that a non-U.S. Certification Authority representative is the Review Team Lead, and FAA personnel are team members. This model has worked well in previous reviews and normally satisfies FAA requirements of the review, if planned accordingly.
