Element Design Assessment (EDA) Self Audit

What is an EDA?

The SAS EDA tool is used to collect data in the form of an Element Design (ED) Data Collection Tool (DCT) to determine if the design of a safety critical process can be approved or accepted.

Why is the applicant encouraged to answer the questions on EDAs?

Completing the EDA DCTs helps the FAA determine if the design of your safety critical processes meet the standards for approval or acceptance, including the requirements to comply with regulations, and allows your personnel to perform their duties and responsibilities with a high degree of safety.

How does the FAA evaluate my EDA submission?

The FAA initially reviews a sample of your submitted EDAs and compares them to your company manuals and system documentation to determine if the answers and references on each EDA are correct and if your process design is eligible for approval or acceptance.

How do I use EDAs?

You can download or print an EDA and review it from <u>Dynamic Regulatory System</u> (<u>DRS</u>):

The **Select DCT tab** tells you the Master List of Function (MLF) number and name, the type of tool (EDA, EPA or SPA), the specialty, the number of questions and the number of completed questions.

The **Prepare DCT tab** has:

- 1. <u>Purpose of the DCT</u> describes your responsibility. These policy statements describe what you intend the process to do. Purpose statements address what is the rule, rather than how to implement the rule.
- 2. Objective describes the FAA's oversight objectives for collecting this data:
 - To determine if your process meets all applicable regulatory requirements and follow FAA policies.
 - To determine to what extent your process design includes the safety attributes.

Each question will contain a list of the regulatory and policy references you must be familiar with:

- Review the Specific Regulatory Requirements (SRR) to understand the regulatory requirements.
- Review Related CFRs and FAA Policy/Guidance contained in the Handbook and other Orders, Advisory Circulars, Legal decisions, and Preambles to understand the intent of the regulation and the inspector work instructions. While you do not

have to "comply" with FAA guidance, the Aviation Safety Inspectors (ASI) are required to follow this guidance and these work instructions when assessing your processes.

There are seven **Safety Attributes**, which cover *procedures*, *controls*, *process measures*, *interfaces*, *safety ownership*, *management responsibility and management authority*. Each question will indicate which Safety Attribute the question applies to.

Each ED DCT has a series of questions that you must answer based on your observations. You must plan the activities that allow you to collect sufficient data to answer the questions accurately.

The activities necessary to answer ED DCT questions will primarily consist of a review of your system documentation for the selected Element. However, there may be occasions when you will want to visit your facilities or airplanes to verify that something in the system design is actually in place and available for use (e.g., a particular simulator or system on the airplane).

Do not use the ED DCT questions to design your processes. You may have all the questions answered "yes," and every reference may be correct, but the information will be disjointed and your employees will not be able to use the information to accomplish their duties and responsibilities with a high degree of safety. Therefore, the process design will not be eligible for approval or acceptance.

How to Answer Questions

ED DCT questions must be answered either "Yes", "No", or "NA" for not applicable. Do not enter a response if you're unsure whether something you observed or reviewed was satisfactory, unsatisfactory, or potentially unsatisfactory. Answer questions based ONLY on what you reviewed or observed.

When and How to Answer "Yes"

A "yes" answer must be all "yes." If any part of the answer is "no," then the question's answer is "no." There is no "maybe" response in SAS. Great care should be taken when determining if the response is positive. If you record a positive answer using a qualifier (e.g., "Yes, but..."), this may indicate that the answer should actually be a "No." In that case you should re-evaluate your answer and perhaps collect additional data.

- If a Supplemental Regulatory Requirements (SRR) or FAA policy and guidance references are included with a question, a "Yes" response indicates that your documented process complies with the SRR attached to the question and/or meets the intent of applicable FAA policy and guidance for that element.
- For questions without an SRR(s), a "yes" answer indicates that your documented process incorporated whatever was the subject of the question.
- For each "yes" answer, you must enter a reference to the location(s) in your system documentation where the information was found. If the reference is to the manual system, it must be to the volume, chapter, and paragraph level (or equivalent).

When and How to Answer "No"

The significance of a "no" response depends on the specific DCT question that is being asked.

- If an SRR(s) or FAA policy and guidance references are included with a question, a "no" response indicates that your documented process does not comply with the specific regulatory requirements (SRR) attached to the question and/or does not meet the intent of applicable FAA policy and guidance for that element.
- For questions without an SRR(s), a "no" answer indicates that your documented process did not incorporate whatever was the subject of the question.
- All "no" responses require a response detail selection and an explanation in the supporting comment field. You should provide enough information for the evaluator to understand the reason why the answer was "no" and why the response detail was chosen.

All applicants and certificate holders have some "no" answers. "No" answers do not automatically equate to an unsafe condition or a regulatory violation, unless that particular "no" answer has a regulatory basis and the documented process includes a possible violation or an unsafe condition. "No" answers fall into one of three categories.

- 1. The first category of "no" answers represents compliance issues that are tied to literal regulatory requirements. The issues associated with these "no" answers will require modifications to the process design.
- 2. The second category deals with "no" answers that do not require any action. For example, a single "no" may be an outlying data point of no consequence or it may represent a hazard with associated risk that is being managed at an acceptable level. Another example in this category is a "no" answer related to a safety attribute that is not significant for approval or acceptance of a system or program or is not essential to the performance of a system or program.
- 3. A final category of "no" answers provides evidence that a process does not meet the intent of a regulation and, therefore, requires you to alter the design of your processes. SAS tools help the FAA describe the system deficiency by referring to the safety attributes and reviewing how the deficiency ultimately relates to the 49 USC requirements for you to be able to identify hazards and manage associated risks. If you do not make acceptable corrections, then it may be appropriate to withhold, or limit or alter operating approvals and authorizations.

When and How to Answer "NA" - Not Applicable

An "N/A" (not applicable) answer means that a particular question does not apply to your requested scope of operation because of the type of operation, type of aircraft, area of operation, etc. An "N/A" answer does not mean "not observed" or that not enough time was available to answer the question. If a question applies to your requested scope of operations, then you must answer it with a "yes" or "no" response.