المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Guidance for completing SFDA On-line MDMA Application Form (Part 2)

American Jurisdiction

قطاع الأجهزة والمنتجات الطبية
إدارة الإذن بالتسويق

Revision: 7-June-2015
Version 2.0

Document History

Version	Modification	date
1.0	Initial draft	26-06-2012
2.0	Updates following first review	29-03-2015

1. Manufacturer

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
1.1	Manufacturer	*DO*	*Select the name of the Manufacturer*
1.2	Legal Manufacturer	*DO*	*Select the name and address of the Legal Manufacturer (Registered Device Manufacturer)*
		CHECK	*The name and address of the Legal Manufacturer of the devices in this application. It must concur with sections:* *2.1.10 Labelling* *2.1.11 IFU,* *2.3 A/C power supply statement – if applicable* *2.4 Environmental statements* *2.5 The provided documents* *5.3 PMA,510(k) or declaration of conformity* *5.4 The amendment letter –if applicable-* *5.7 Establishment registration and device listing evidence* *6.4 Recent EIR* *6.6 The most recent audit report – if applicable-* *7.1 Regulatory Compliance Attestation*
		WARNING	*A common error is to insert the device manufacturers site address, rather than the Legal Manufacturer address* *If the Legal Manufacturer has two addresses, a Postal Address and a Site Address, please provide an attested letter from the Legal Manufacturer explaining that there are two addresses. – Insert the letter in section 5.3*
1.3	Medical Device Category	*DO*	*Use SFDA drop-down list of 17 categories*
		CHECK	*That all the devices in the application fall under the selected category.*

2. General Info.

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
2.1	Details of the medical devices applying for market authorisation (open the list below)	*DO*	*Insert the list of devices in the application*
		CHECK	*Cross check the list of devices against* *2.1.10 Labels* *2.1.11 IFU* *5.3 PMA,510(k) or declaration of conformity* *5.4 The amendment letter –if applicable-* *5.7 Establishment registration and device listing evidence* ***Refer to SFDA BUNDLING Rules in MDS-G7:*** *http://www.sfda.gov.sa/en/medicaldevices/regulations/DocLib/MDS-G7.pdf* *If a device has multiple models (with the same brand name),*

<table>
<tr><th>No</th><th>SFDA Question</th><th>DO
CHECK
WARNING</th><th>Task</th></tr>
<tr><td></td><td></td><td></td><td>for example Male Urinary Catheters of different sizes, the applicant should include these in one line.

<table><tr><td>Product Description</td><td>Intended Purpose</td><td>Trade/Brand Name</td><td>Model Number</td></tr><tr><td>Male Urinary Catheters</td><td>Drain urine from the bladder</td><td>XYZ</td><td>123-40
123-50
123-60</td></tr></table></td></tr>
<tr><td>2.1.1</td><td>Product Brief Description</td><td>DO</td><td>Insert the Product Description

Note: The Product Description will be printed on the MDMA License issued by the SFDA.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>The Product Description must be precise and informative (maximum of 100 characters).
In English only, no commas (accept if it makes sense (part of the sentence) ex.: infant, paediatric & adult ventilator), clear and accurate.
No spelling or typing errors
No Brand Names or Company Names</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>“Catheter, Urinary” will be rejected whereas “Urinary Catheter” is acceptable

Classification from FDA used as product description is not accepted. i.e. “Respirator, mask, surgical”

Do Not include Brand Names or Company Names</td></tr>
<tr><td>2.1.2</td><td>Intended purpose of the medical device type (mandatory)</td><td>DO</td><td>Insert the intended purpose.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>Typically this is an extract from the IFU</td></tr>
<tr><td>2.1.3</td><td>Trade/Brand Name (as it appears on the label)</td><td>DO</td><td>Insert the device Trade/Brand Name

Note: The device Trade/Brand Name will be printed on the MDMA License issued by the SFDA.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>The device Trade/Brand Name must be IDENTICAL to the Trade/Brand Name as it appears on the device Label</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>The Trade/Brand Name inserted in section 2.1.3 will be printed on the MDMA License issued by the SFDA. If it does not match the Trade/Brand Name on the label, it may cause delays at the Port of Entry or complete refusal</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>The combination of the Product Description and Trade/Brand Name must be unique for every device listed in the application.</td></tr>
<tr><td>2.1.4</td><td>Model Number (as it appears on the label)</td><td>DO</td><td>Insert the Model Number</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>If the product has a model/Ref number, the brand name must</td></tr>
</table>

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			not be repeated in this section
		CHECK	*If more than one Model Number is listed in a window, these models should only differ in either colour, size, weight or dimensions.* *Check it concurs with the product model number as it appears on the product Label*
2.1.5	Manufacturer's Device Identifier Number (mandatory)	*DO*	*Insert the Manufacturers Device Identifier Number(s)*
		CHECK	*Typically this is the REF number, or Product catalogue number* *Check it concurs with the product ID number as it appears on the product Label*
		CHECK	*If a device has multiple models with the same Product Description, Intended Purpose and Brand Name, for example Male Urinary Catheters of different sizes, the applicant should include these here.*
		WARNING	*The SFDA will is issue the MDMA License only for the models/sizes listed in section 2.1.5*
2.1.6	Format of medical device identifier number(s) that will appear on labelling for traceability purposes	*DO*	*Insert the Format of medical device identifier number(s) that will appear on labelling for traceability purposes*
		CHECK	*Typically this is the LOT number, or Serial number* *Provide a brief description of how the number is formatted* *Eg LOT YYYY-MM-DD (year-month-day)* *It is indicated on the provided label*
2.1.7	GMDN	*DO*	*Insert the GMDN code number if available*
2.1.8	UMDNS	*DO*	*Insert the UMDNS code number if available*
2.1.9	Other (e.g. FDA identification number, JMDN)	*DO*	*Insert the Other code numbers if available*
2.1.10	Provide the label(s) affixed to the device or its wrappers when it is supplied to the KSA.	*DO*	*Attach the device labels for ALL devices listed in this section* *A/C Power Supply* *If the product is connected to an A/C power supply, the applicant must provide images of the power supply label, so it can be cross-checked with the A/C Power Supply signed declaration provided in section 2.3(60 Hz supply at nominal values of either 230 or 400 volts)* *This is a USA submission therefore labels must be compliant with US-FDA Regulations* *For IVD Kits, all the individual reagent labels must be provided.*

<table>
<tr><th>No</th><th>SFDA Question</th><th>DO
CHECK
WARNING</th><th>Task</th></tr>
<tr><td></td><td></td><td>CHECK</td><td>
Labels are provide for ALL the devices listed in this section

Including each of the model numbers/REF/Part No./etc

When the device has a range (eg sizes) then
a representative label for each brand name is acceptable with a table that clearly links one product-size to one product ID number.

Example (Acceptable)
<table>
<tr><td>Trade Name</td><td>REF
(Product ID Number)</td><td>Size
(product variable)</td></tr>
<tr><td>Medical Device</td><td>1234</td><td>5x5cm</td></tr>
<tr><td>Medical Device</td><td>1236</td><td>10x10cm</td></tr>
</table>
The applicant has provided a clear link between each of the product ID numbers and the product sizes/dimensions

The table must be from the Legal Manufacturer and must be signed, job title & dated

The Labels must contain:
Device Trade Name (see 2.1.3)
Device model Number (see sec 2.1.4)
Device ID Number (REF) (see 2.1.5)
Legal Manufacturers Name & Address (see 1.1 & 1.2)

In addition it may also contain:
LOT or Serial Number
Power Supply – if applicable (60 Hz supply at nominal values of either 230 or 400 volts)
Storage Temperature
Expiry Date
Date of Manufacture
Sterile & Method – if applicable
Single Use – if applicable
The term “Made in.....” with country of origin.
IVD – if applicable
IVD Self Test – if applicable
Rx only, if applicable

Note: If the device is for Professional Use only
The label in English only is acceptable
Reference: SFDA MDS-IR6 Article 9 (C)

Note: If the device is for Home Use / Self Test IVD
The label must be in both English & Arabic
Reference: SFDA MDS-IR6 Article 9 (C)
</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>A common error is wrong or missing labels</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>
Tables-
Example (Not Acceptable)
<table>
<tr><td>Trade Name</td><td>REF
(Product ID Number)</td></tr>
<tr><td>Medical Device</td><td>1234
1236
etc</td></tr>
</table>
</td></tr>
</table>

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			The applicant has provided no link between the product ID numbers and the product sizes/dimensions. *The label shall not include the SFDA logo, SFDA name or MDMA license number.*
2.1.11	Provide the 'instructions for use' document intended for KSA users of the medical device. - If NOT RELEVANT provide a justification*. (See below)	*DO*	*Attach the IFU for ALL the devices listed in this section* *This is a USA submission therefore the IFU must be compliant with the US-FDA Regulations.*
		CHECK	*IFU cover ALL the devices Trade/Brand Names listed in this section* *Legal Manufacturers name and address are printed on the IFU and concurs with section 1.1 & 1.2* *Electrical rating –if applicable-.* ***Note: If the device is for Professional Use only*** *The IFU in English only is acceptable* *Reference: SFDA MDS-IR6 Article 9 (C)* ***Note: If the device is for Home Use / Self Test IVD*** *The IFU must be in both English & Arabic* *Reference: SFDA MDS-IR6 Article 9 (C)* *- Any warnings and/or precautions to take.* *The IFU must have Date of Issue or the latest Revision Number* *Device models and IDs (must match with 2.1 – if mentioned). If the IFU does not cover all models or IDs or does not match with sections 2.1.4 and 2.1.5, a justification* is required.* *Storage Temp: Min & Max (where required)* *Sterility method:(where required)* *- Single use: (where required)* *Power requirement if applicable (60 Hz supply at nominal values of either 230 or 400 volts).*
		WARNING	*A common error is a wrong or missing IFU*
	If NOT RELEVANT provide a justification*	*DO*	*If its NOT RELEVANT to have an IFU for the device, then the applicant MUST provide a justification*.*
		CHECK	*The justification* must be from the Legal Manufacturer and must be signed, job title & dated*
		WARNING	*The justification* must be from the Legal Manufacturer and must be signed, job title & dated*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
2.1.12	**List of Accessories**	***DO***	***List the Accessories for this device***
		CHECK	***Definition: Accessories are devices specifically intended by its Legal Manufacturer to be used together with the medical device to achieve its intended purpose.***
		WARNING	***If the Accessory can be used as a stand-alone medical device, the SFDA do NOT consider it an Accessory. It must be listed as a Medical Device***
2.2	Jurisdiction(s) where this medical device may be placed on the market. • Australia • Canada • Europe • Japan • USA	*DO*	*Make the selections as appropriate.*
		CHECK	*USA must be selected because this is a USA submission*
2.3	If the device is connected to an a/c power supply, provide a statement that confirms it is: 1. designed to operate with a 60 Herz supply at nominal values of either 230 or 400 volts; 2. is fitted with the appropriate a/c power connector; 3. maintains the required electrical safety conditions 4. continues to perform to specification.	*DO*	*if it is not applicable select the (N/A) box and move to the next section.* *If the device/accessory is connected to an a/c power supply, complete the statement Template provided* ***Printed on the <u>Legal Manufacturers</u> Letterhead*** *The statement must be from the Manufacturer and must be signed, job title & dated*
		CHECK	*The statement must be from the Legal Manufacturer and must be signed, job title & dated*
		WARNING	*The statement must be from the Legal Manufacturer and must be signed, job title & dated* *Do NOT alter the wording of the SFDA Template*
2.4	Provide a statement that the device will perform as intended when subjected to other environmental factors encountered within the KSA	*DO*	*Complete the statement Template provided* ***Printed on the <u>Legal Manufacturers</u> Letterhead*** *The statement must be from the Manufacturer (Letterhead) and must be signed, job title & dated*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
		CHECK	*The statement must be from the Legal Manufacturer and must be signed, job title & dated*
		WARNING	*Common error is to include extra devices that are not listed in section 2.1* *Do NOT alter the wording of the SFDA Template provided. Adding statements to the SFDA Template might be acceptable if the added information concur with IFU*
2.5	Provide a copy of the manufacturer's instructions to ensure that the medical device intended to be placed on the KSA market will be correctly stored, transported, installed, maintained & disposed of, and that users can be trained in their proper use and maintenance.	*DO*	*Provide a copy of the manufacturer's instructions to ensure that the medical device intended to be placed on the KSA market will be correctly stored, transported, installed, maintained & disposed of, and that users can be trained in their proper use and maintenance.* *The applicant may also provide additional information that they consider relevant to this request. The additional information must be from the Legal Manufacturer (Letterhead) and must be signed, job title & dated, and only list devices and accessories Trade/Brand Name in this application(see 2.1) or the application number.*
2.6	Provide a copy of the manufacturers advertising and marketing material intended for use in the KSA	*DO*	*Attach a copy of the marketing literature for at least ALL the devices listed in section 2.1* *Note: It is acceptable for the marketing material to include more devices than what is listed in section 2.1* *Note: A product catalogue (soft copy "online or offline" or a scanned hard copy) is considered marketing material and it is acceptable.*
		CHECK	*Marketing literature is provided for at least ALL the devices listed in section 2.1* *It is acceptable for the marketing material to include more devices than what is listed in section 2.1* *The marketing literature must include the name of Legal Manufacturer. But it is not necessary to have the address of the Legal Manufacturer on the marketing literature* *Marketing Literature must have a document control reference number/code.* ***Note: If the device is for Professional Use only*** *The marketing literature in English only is acceptable* *Reference: SFDA MDS-IR6 Article 9 (F)* ***Note: If the device is for Home Use / Self Test IVD*** *The marketing literature must be in both English & Arabic* *Reference: SFDA MDS-IR6 Article 9 (F)*
		WARNING	*Include marketing literature for at least ALL the devices listed in section 2.1*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			Include the Name of the Manufacturer *A common error is to state there is no marketing literature when a product catalogue is available* *A common error is to provide a marketing material without a document control reference number* *Another common error is to state there is no marketing literature when the Legal Manufacturers webpage, which is accessible in the Kingdom of Saudi Arabia, contains marketing literature for the devices listed in the application.*
	• if NOT AVAILABLE provide an explanation and the date when such material will become available	*DO*	*If Marketing Literature is NOT AVAILABLE provide both an explanation and the date when such material will become available* *Note: A product catalogue (on-line or printed) is considered marketing material and is acceptable.*
		CHECK	*The explanation must be from the Legal Manufacturer (Letterhead). It must state why the marketing literature is currently not available. It must state when (date) it will become available. The explanation must be signed, job title and dated.*
	• If NOT REQUIRED provide a justification*	*DO*	*If Marketing Literature is NOT REQUIRED provide a justification** *Note: A product catalogue (on-line or printed) is considered marketing material and is acceptable.*
		CHECK	*The justification* must be from the Legal Manufacturer (Letterhead) and must be signed, job title and dated.*

3. Jurisdiction

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
3.1	Desired Jurisdiction	*DO*	*Ensure the USA jurisdiction has been selected*

4. Product Categories (USA)

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
4.1	Device Type • Medical Device • IVD	*Do*	*Select one option*
		CHECK	*The selected Device Type complies with the devices listed in section 2.1*
4.2	Device Classification	*DO*	*Select one option*

	Medical Devices • Class I • Class II • Class III • Unclassified devices IVD • Class I • Class II • Class III • Unclassified devices		
		CHECK	*The selected Device Classification complies with the devices listed in section 2.1* *The Device Classification concurs with the provided evidence(s) in section 5.*

5. Product Verification (USA)

No	**SFDA Question**	***DO*** ***CHECK*** ***WARNING***	***Task***
5.1	Indicate pre-market submission status of the medical device • PMA • 510(k) • Class I Exempt • Class II Exempt	*DO*	*Please tick the appropriate pre-market submission status*
		CHECK	*The selected pre-market status is correct for the specific device(s) in this application*
5.2	Provide the product code allocated by the FDA	*DO*	*Provide the product code allocated by the FDA*
		CHECK	*Confirm the selected product code is correct for the specific device(s) in this application against the uploaded document in 5.3 and FDA data base.* *See the FDA webpage:* *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm*
5.3	Provide the current 510(k) or PMA approval letter authorising the marketing of the device, where relevant	*DO*	*Provide the current 510(K) or PMA approval letter authorising the marketing of the device, where relevant*
		CHECK	*Confirm the 510(k) or PMA letter has been provided (if required), or the declaration of conformity if the device is Exempt.* *Check the FDA webpage to confirm the 510(k) or PMA is correct for the specific device(s) in this application*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			For 510(k) see: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm *For PMA see: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm* *Check the FDA webpage to confirm the 510(k) or PMA is correct for the Legal Manufacturer (name & address)* *If the name or address the 510(k) or PMA letter is different to the Legal Manufacturer name and address provided in section 1.2, please provide an attested justification* from the Legal Manufacturer, signed, job title and dated.*
		WARNING	*If the name or address the 510(k) or PMA letter is different to the Legal Manufacturer name and address provided in section 1.2, please provide a justification* from the Legal Manufacturer, signed, job title and dated.*
5.4	Provide the amendment letter(s) where CDRH has issued amendments to the original 510(k) or PMA approval letter.	*DO*	*Provide the amendment letter(s) where CDRH has issued amendments to the original 510(k) or PMA approval letter.*
		CHECK	*Confirm that the letters have been provided (if required)* *Confirm that the letters are for the specific device(s) in this application*
5.5	Provide the name and affiliation of the Accredited Person under the Accredited Person Programme responsible for reviewing the 510(k), if such was involved	*DO*	*Ignore this questions if an Accredited Person was NOT involved in 510(k) review* *Provide the name and affiliation of the Accredited Person under the Accredited Person Programme responsible for reviewing the 510(k), if such was involved.*
		CHECK	*Confirm that the name and affiliation of the Accredited Person has been provided* *See: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/Accredit.cfm*
5.6	If the device is Class I exempt or Class II exempt, indicate the location of the technical information that demonstrates that the device is safe and performs as intended by the manufacturer	*DO*	*Confirm the device is Class I exempt or Class II exempt* *Confirm that the location is provided*
		CHECK	*Confirm that the technical information is stored at the location provided to the SFDA*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
5.7	Provide evidence that the manufacturer has complied with FDA's 1- Establishment Registration 2- Device Listing.	*DO*	*Provide evidence of Establishment Registration and Device Listing*
		CHECK	*Confirm that the evidence has been provided* *The device name, manufacturer name, premarket submission number and product code.* *Confirm that the data is for the current year.* *Confirm the data provided concurs with the information on the FDA database* *See:* *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm* *If the name or address the 510(k) or PMA letter is different to the Legal Manufacturer name and address provided in section 1.2, please provide an attested justification* from the Legal Manufacturer, signed, job title and dated.*

6. Manufacturers QMS Status (USA)

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
6.1	Indicate whether the manufacturer of the medical device operates an establishment quality management system (QMS) that is acceptable to the FDA • Yes • No	*DO*	*Select one answer*
6.2	Indicate the type of QMS used	*DO*	*Insert the Quality Management Standard*
		CHECK	*This application is under the US-FDA Regulations. Therefore the FDA 21 CFR 820 Quality System Regulations are applicable unless QSR is exempted for the device(s)*
6.3	Indicate the procedure(s) that are included within the Manufacturers QMS • Design and development	*DO*	*Select one or more*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
	• Manufacturing • Manufacture of sterile devices		
		CHECK	*Confirm that one or more has been selected* *Confirm the data provided against the FDA database* *See:* *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm*
6.4	Where the QMS has been audited by the FDA, provide evidence of the most recent audit	*DO*	*Confirm a full copy of the Establishment Inspection Report (EIR) has been provided* *Confirm the Manufactures name and address are correct* *If EIR not provided, a justification* from the legal manufacturer must be provided.*
		CHECK	*Confirm that the Establishment Inspection Report is for the Legal Manufacturer*
6.5	Provide the date of the most recent audit by either the FDA or Accredited Person	*DO*	*Provide the date of the most recent audit by either the FDA or Accredited Person*
		CHECK	*Confirm the date has been provided* *Confirm that it tallies with the date provide in 6.4 (if available)* *Confirm that the date is the latest one issued by either FDA (section 6.4) or Accreditation Person (section 6.6)*
6.6	Where the QMS has been audited by an Accredited Person, provide the evidence of the most recent audit	*DO*	If the QMS has been audited by an Accredited Person, provide the evidence of the most recent audit. *If the most recent EIR is not provided, provide evidence from the FDA that the most recent audit report issued by the* Accredited Person is accepted.
		CHECK	*Confirm the evidence has been provided* *Confirm the Legal Manufactures name and address are correct*
6.7	Name of the Accredited Person responsible for the QMS audit	*DO*	*Provide the name of the Accredited Person responsible for the QMS audit*
		CHECK	*Confirm the name has been provided*

7. Other National Provisions

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
7.1	Provide an attestation written in English, to declare that each clearly identified medical device covered in this application complies with the medical device regulations that apply within the GHTF Founding Member jurisdiction that has been selected as the basis of the application and with the specific KSA national provisions within the Medical Devices Interim Regulation. (SFDA Template provided)	*DO*	*Complete the attestation using the template provided* *The attestation must be printed on the* ***Legal Manufacturers Letterhead*** *GHTF Regulation: Select USA* *The statement must be from the Manufacturer and must be signed, job title & dated* *Manufacturer name & address* *Signed:* *Job Title:* *Dated:*
		CHECK	*Only USA has been selected as the GHTF Regulation.* *The attestation must be from the Legal Manufacturer and must be signed, job title & dated*
		WARNING	*This is a USA submission, therefore only USA must be selected.* *The attestation must be from the Legal Manufacturer and must be signed, job title & dated*
7.2	Provide the address of the location where the manufacturer holds technical information to support this attestation.	*DO*	*Provide the address of the location where the Legal Manufacturer holds technical information to support this attestation.*
		CHECK	*It must be a full postal address (ex: building number, road, city, postal code, state, country)*
7.3	Signature of the person responsible for completing this application (A)	*DO*	*Complete the attestation using the SFDA template provided* *The attestation must be printed on the* ***Authorised Representative (AR)/ Local Manufacturers (LM) Letterhead*** *Application Number:* *AR/LM Company name & address in English (Arabic and English is acceptable):* *Signed:* *Job Title:* *Dated:* *AR ID Number:*
		CHECK	*The correct application number has been provided.*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			The name & address of the AR or LM has been provided And the attestation signed, job title and dated *The date of the attestation must not be older than one month from the date of submitting the application*

Notes:

* All justifications are subject to SFDA evaluation.

** The SFDA may ask for additional technical documentation before reaching its decision if such is required but, where it does so, provide a justification* for the request. (*MDS- G5*)

-END-