EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Handling of requests for access to information		
Status: **PUBLIC**		Document no.: SOP/EMA/0019
Lead author	Approver	Effective date: 11-NOV-2019
Name: Elfa Eihenbauma	Name: Guido Rasi	Review date: 11-NOV-2022
Signature: On File	Signature: On File	Supersedes: SOP/EMA/0019 (24-JUL-15) SOP/H/3386 (11-NOV-16)
Date: 11-NOV-2019	Date: 11-NOV-2019	TrackWise records no.: 5423

1. Purpose

The purpose of this SOP is to define the procedure for the handling of requests for information received in writing at the Agency. Requests received by phone are not included in the scope of this SOP.

"Requests for information" (RFIs) shall mean external requests requiring an answer from the Agency and not falling within the scope of Regulation 1049/2001 (access to documents). These requests shall be handled in accordance with the European Medicines Agency Code of Good Administrative Behaviour.

An RFI is therefore a request from a third party received by the Agency pertaining to knowledge and/or information that the Agency may hold and which **cannot** be considered as:

- A request falling under the scope of Regulation (EC) No 1049/2001 (ATD). The definition of a request for documents is included in the legislation and in the Agency's policy (Policy 043).

  On this basis and in accordance with the current case-law, ATDs are also any requests for data from databases (e.g. EudraVigilance) that would result in an exact copy of all or part of the information contained therein being included in a file or document that is produced by a normal and/or routine query to the database. However, if the request entails a substantial intellectual effort and significant amount of work that goes beyond a normal or routine search (e.g. running a number of searches and/or compiling manually the information that is subject to the request and/or linking data between databases), such a request must be considered an RFI. Therefore, aggregation of records to produce numbers or similar operations to produce summaries and/or breakdowns of information contained therein, should be considered as RFIs, as they are not copies of documents or part of documents sent to the database.

- A core business request. This is a request/query related to a specific procedure and submitted by one of the parties involved in that procedure. This includes all regulatory procedures, but also others, such as procurement procedures. EV data provisions for an EMA regulatory procedure to

MAHs and as part of data exchange agreements with other regulatory agencies are business cases and not ATDs. Exchanges with registered stakeholders made by the relevant Departments and Divisions of the Agency are also considered core business.

- A request from an NCA, the European Commission (EC), FDA or another organisation with which a confidentiality agreement, memorandum of understanding, contractual arrangements or other agreement are in place which allow for a privileged exchange of information related to the business of the Agency.
- RFIs from journalists received directly by the Press Office and dealt with by the Press Office are excluded as well from this SOP.

2. Scope

This SOP only concerns RFIs received in writing, either in electronic or hard copy (i.e. letter or fax) format. Requests received by phone shall be addressed in a separate SOP.

The Agency shall respond to RFIs "*within a reasonable time limit, without delay, and in any case no later than two months from the date of receipt*" in accordance with Article 18 of the European Medicines Agency Code of Good Administrative Behaviour. The Agency is, however, setting shorter deadlines for lower risk and less complex requests (please see Table 1.).

In cases where the distinction between requests for access to information and requests for access to documents (mixed requests) can be made easily, the request may be split and for each subset the respective procedure must be followed. Replies will be sent out as and when each subset has been finalised.

In cases where the request is of a complex nature, a stepwise approach will be taken where necessary, and replies sent out as and when they have been finalised.

3. Responsibilities

It is the responsibility of each Head of Division, Head of Department, Head of Service and Head of Office to ensure that this procedure is adhered to within their respective Division, Department, Service or Office. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of point 9. Procedure.

4. Changes since last revision

The SOP was updated to reflect the latest changes in the organisation chart and the outcome of the audit on RFIs conducted in 2016. The scope has also been widened to the whole Agency and now also incorporates SOP/H/3386 which covered RFIs received from patients, healthcare professionals, academia and the general public.

5. Documents needed for this SOP

All documents are located in Document Records Electronic Archive Management (DREAM) in Cabinets/09. Relationship management and communication/09.7 ATD & RFI/Requests for information/02 Reports and work reference documents.

- EMA/212834/2014 – Dispatch channels for RFIs (internal procedure document).

6. Related documents

All documents are published on the EMA public website:

- European Medicines Agency Code of Good Administrative Behaviour;
- Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents;
- Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters to Community institutions and bodies
- EMA/110196/2006 – POLICY/0043 - European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use) (under review);
- EMA/127362/2006 Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use (under review).
- EMA/38179/2014 Press and media manual (a controlled document, approved via WIN/EMA/0143).

The documents under review will be adopted in the coming months. The latest version should always be consulted.

7. Definitions

Please note that the definitions below are valid at the time of the effective date of this SOP. For the most up-to-date definitions please refer to the document listed under **5. Documents needed for this SOP.**

AskEMA	The AskEMA management tool (JIRA) is used to track all RFIs received directly via the web form[1], or exceptionally entered manually into the system. Each request is allocated a unique reference number. The start date the deadline and the response are also recorded and tracked in AskEMA.
DED-DAP	Deputy Executive Director – Documents Access and Publication Service.
Document	Any content, whatever its medium (written on paper or stored in electronic form or as a sound, visual or audio-visual recording) concerning a matter relating to the policies, activities and decisions falling within the Agency's sphere of responsibility.
List of Responsibilitites	Each of the Divisions will publish on the relevant internal webpages or databases a list of the Staff Member(s) responsible for, or in charge of, a particular task or product.
Releasable	Any document that can be released in accordance with the Regulation (EC) 1049/2001 is considered releasable. Documents not classified as confidential are considered public.
Requester	Any person requesting general information from EMA.
Triager	Designated member within DED-DAP responsible for the triage and dispatch of RFIs

[1] http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=WC0b01ac05806499f0

Topic Coordinator	Designated member within each Service/Department/Division responsible for the coordination of RFIs assigned to his/her dashboard.
Responder	Staff member tasked with responding to a query
Contributing staff member	Staff member tasked with providing input to a query.
Third Party	Any person or any entity outside the Agency. This includes Member States, other EU or non-EU institutions and bodies, and third countries.
Approver	Staff member responsible for doing the quality review. Approvers are to be determined in each Division/Department/Service/Office for the queries under their responsibility. For cross-agency queries or level 4 queries, this will be determined on a case-by-case basis to ensure the appropriate expertise and authority level within the Agency.
Quality review	Check done by the approver to ensure that the draft response addresses the question accurately, completely, clearly and in a language appropriate to the requester (for example, a technical response using scientific terms would not be appropriate for a patient)
RFI team	Team within DED-DAP responsible for triaging
Risk level	Risk level for RFIs is a number assigned depending on the complexity of the request, its sensitivity and whether a shorter deadline is needed. The following levels and associated deadlines are established: – Level 1 - Noncomplex, low sensitivity - 15 working day deadline These are simple RFIs such as dates of meetings or location of documents on the website. Since these queries have low sensitivity, a quality review of the answer is not necessary. Examples (not exhaustive list): Where can I buy medicine X? When is the meeting X? Where is the X document published? How can I apply for a job at the Agency?, or communication of broken links on the Agency's webpage or errors in documents on the webpage. – Level 2 –Complex, low to medium sensitivity - 2 calendar-month deadline These are more complex requests that may require input from other colleagues at the Agency ("contributing staff member") and should be quality checked by the approver. Examples (not exhaustive list): Why did you suspend medicine X? What was the evidence behind the decision on referral x? What is the status of the evaluation of medicine X? Can X cause this side effect? How do you interpret scientific guideline X? and questions related to GxP. – Level 3 – High sensitivity with or without complexity - 2 calendar-month deadline These are requests that may require input from several colleagues

across the Agency. In addition to possible complexity, the queries are sensitive and therefore require a review by a manager (head of service or above).

Sensitivity here is defined by requester and/or circumstances.

– Level 4 – Complex and very high sensitivity - 30 calendar-day deadline or custom deadline

These requests should be infrequent as they relate to complex, highly sensitive issues that require a robust response and need managerial guidance. Given the urgency of the issue, the response should be sent out within 30 days or earlier. Cross Agency input is likely and a quality review from senior management (Head of Division and/or Head of Legal) is required.

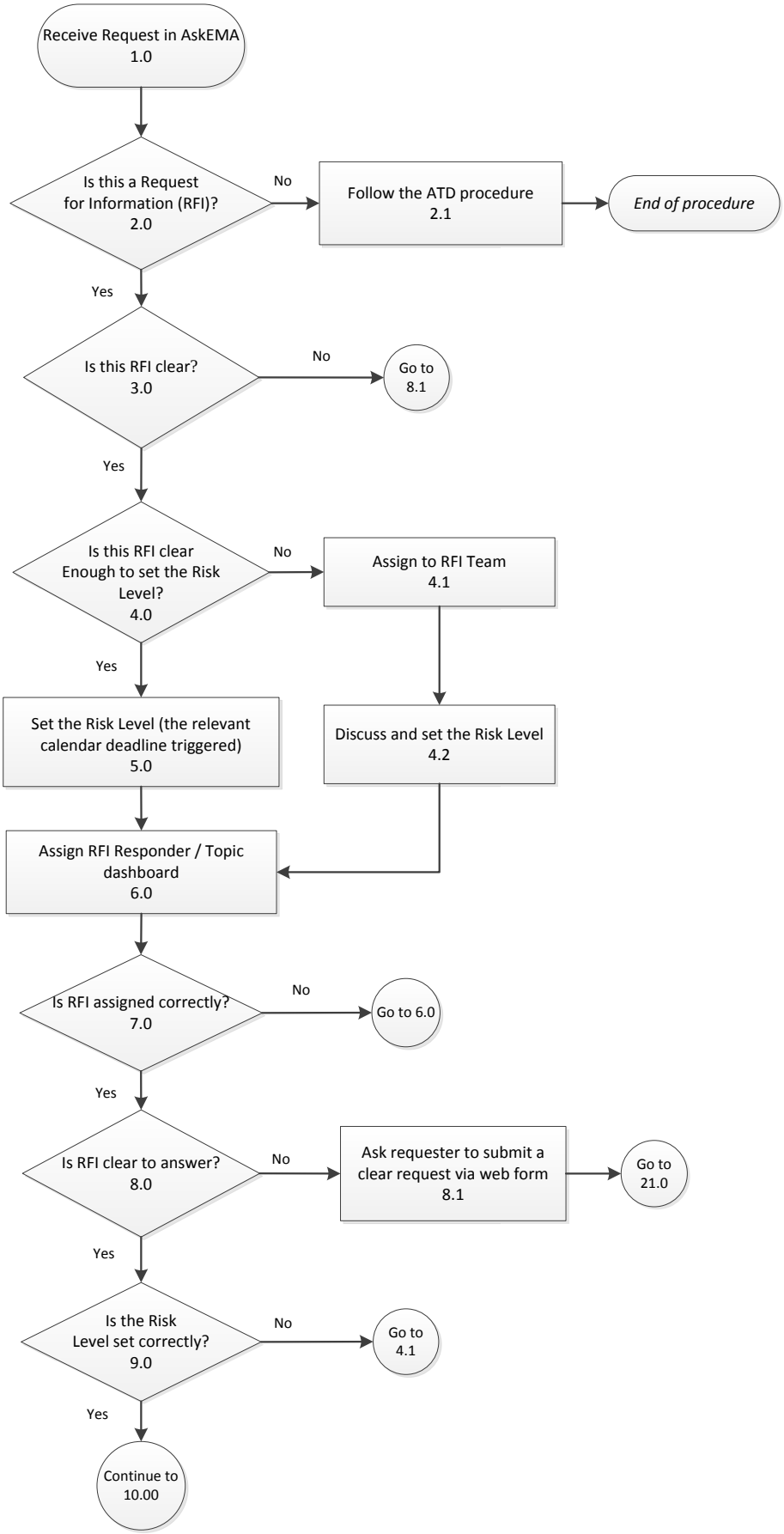
Examples: issues with important presence in the media, issues with legal implications, public health matters.

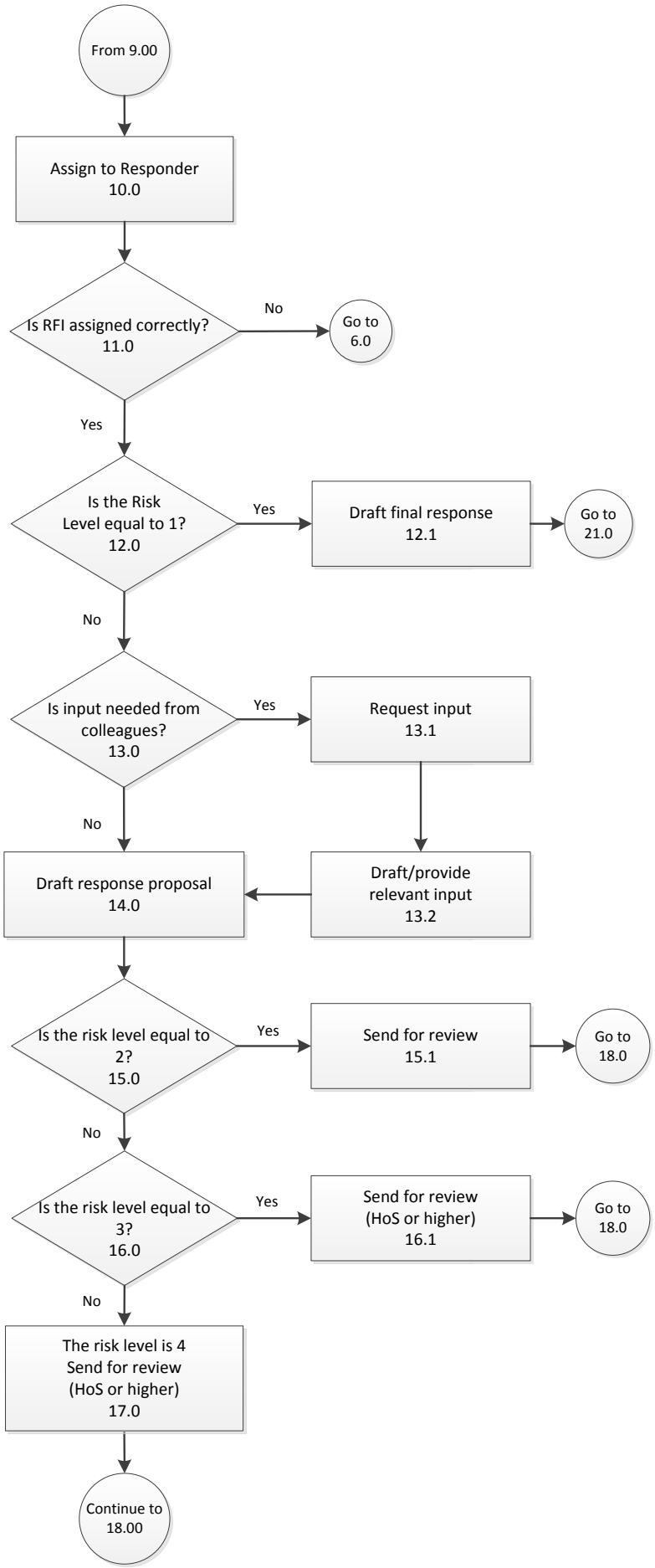
	Level 1	**Level 2**	**Level 3**	**Level 4**
Complex	No	Yes	Yes or No	Yes
Sensitivity[2]	Low	Low or medium	High	Very High
Review level	Not needed	Designated staff member or Head of Service	Head of Service and/or Head of Department or higher	Head of Division, potential involvement of Head of Legal
Deadline	15 working days	2 calendar months	2 calendar months	Custom deadline with a maximum of 1 calendar month

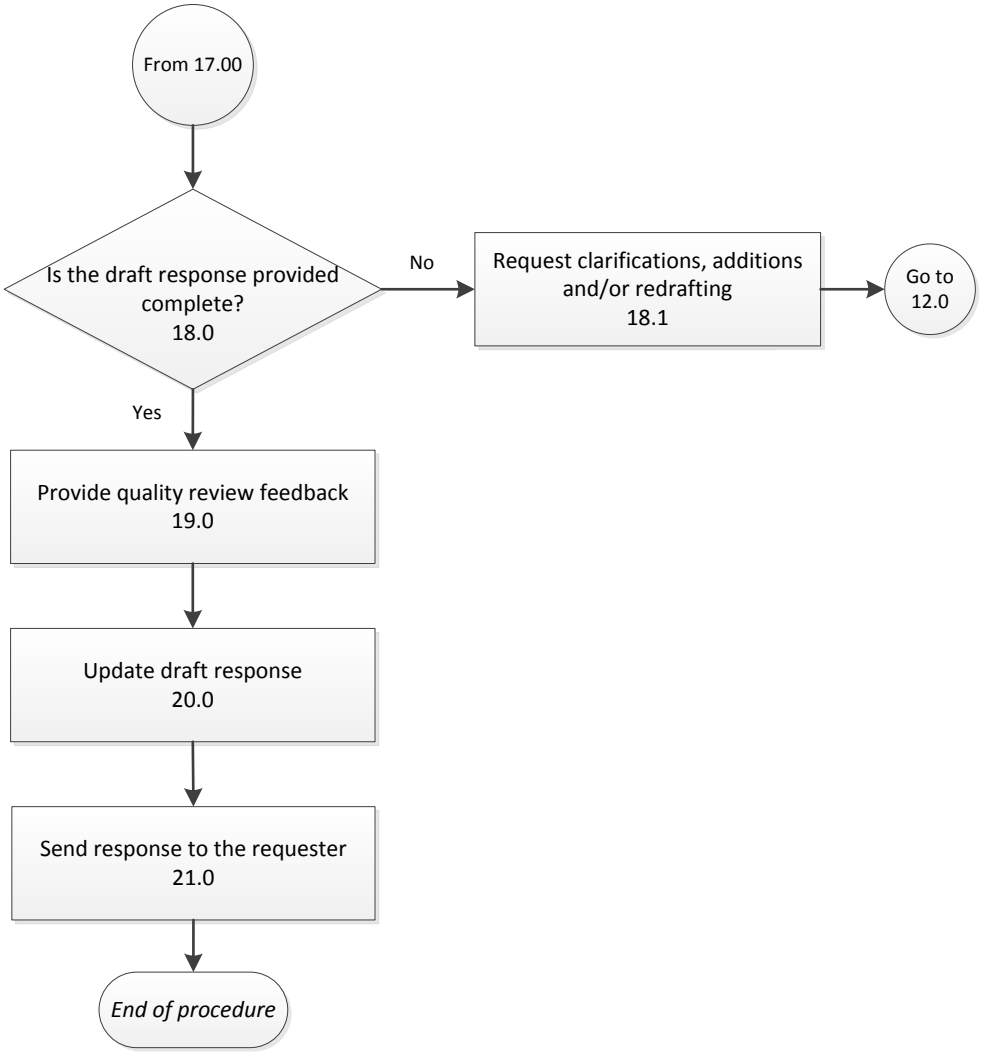
Table 1.

[2] If a query is in one of the following categories, it is sensitive:
- Controversial topic
- Politically sensitive
- High reputational impact
- Public health issue

8. Process map




From 9.00
Assign to Responder
10.0
Is RFI assigned correctly?
11.0
No
Go to
6.0
Yes
Is the Risk
Level equal to 1?
12.0
Yes
Draft final response
12.1
Go to
21.0
No
Is input needed from
colleagues?
13.0
Yes
Request input
13.1
No
Draft response proposal
14.0
Draft/provide
relevant input
13.2
Is the risk level equal to
2?
15.0
Yes
Send for review
15.1
Go to
18.0
No
Is the risk level equal to
3?
16.0
Yes
Send for review
(HoS or higher)
16.1
Go to
18.0
No
The risk level is 4
Send for review
(HoS or higher)
17.0
Continue to
18.00


From 17.00
Is the draft response provided complete?
18.0
No
Request clarifications, additions and/or redrafting
18.1
Go to 12.0
Yes
Provide quality review feedback
19.0
Update draft response
20.0
Send response to the requester
21.0
End of procedure

9. Procedure

Step	Action	Responsibility
1.0	*Start of Deadline* Receive request in AskEMA via webform or exceptionally entered manually into the system. Then go to 2.0	Triager
2.0	Is this a RFI? If necessary, consult the triaging team within the ATD team. If yes, automatic acknowledgment is sent and then go to 3.0. If no: • If it is an ATD, go to 2.1 and follow the steps for the ATD procedure. • If it is SPAM or an abusive requests, the triager will close the request in AskEMA making a note with the reason, if necessary. *End of procedure*	Triager
2.1	Follow the steps for ATD procedure. This is not a RFI and the responsibility passes to ATD coordinator/manager. *End of procedure*	Triager ATD manager/ coordinator
3.0	Is this request clear? If yes, go to 4.0 If no, send to the relevant topic coordinator and go to 8.1	Triager
4.0	Is the request clear enough to set the Risk Level? If yes, go to 5.0 If no, go to 4.1	Triager
4.1	Assign to RFI Team Then go to 4.2	Triager
4.2	Based on the discussion within the RFI team, Set the Risk Level (that will trigger relevant calendar deadline) and establish the responder/topc dashboard. Then go to 6.0	RFI team
5.0	Set the Risk Level (that will trigger relevant calendar deadline). Then go to 6.0	Triager

6.0	Assign request to the relevant Responder / topic dashboard. Then go to 7.0	Triager
7.0	Is this request assigned correctly? If yes, go to 8.0 If no, go back to 6.0	Topic Coordinator
8.0	Is this request clear enough to answer? If yes, go to 9.0 If no, go to 8.1	Topic Coordinator
8.1	Ask requester to re-submit clear request via the webform. Then go to 21.0	Topic Coordinator
9.0	Is the Risk Level set correctly? If yes, go to 10.0 If no, reject the request and assign to the RFI team, go back to 4.1	Topic Coordinator
10.0	Assign to Responder Then go to 11.0	Topic Coordinator
11.0	Is the request assigned correctly ? If yes, go to 12.0 If no, go back to 6.0	Responder
12.0	Is the Risk Level equal to 1 ? If yes, go to 12.1 If no, go to 13.0	Responder
12.1	Draft final response and go to 21.0	Responder
13.0	Is input needed from colleagues ? If yes, go to 13.1 If no, go to 14.0	Responder
13.1	Request input from internal colleague. In some cases, it may be necessary to prepare a first draft prior to sending it to the relevant colleague (contributing staff member) Then go to 13.2	Responder
13.2	Draft/provide relevant input. Then go to 14.0	Contributing staff member
14.0	Draft/update response proposal with or without input provided. Then go to 15.0	Responder

15.0	Is the risk level equal to 2? If yes, go to 15.1 If no, go to 16.0	Responder
15.1	Send draft response proposal for review to the approver Then go to 18.0	Responder
16.0	Is the risk level equal to 3? If yes, go to 16.1 If no, go to 17.0	Responder
16.1	Send Draft Response Proposal for review to approver (Head of Service or higher). Then go to 18.0	Responder
17.0	Risk level is equal to 4 Send draft response proposal for review to approver (senior management).Then go to 18.0	Responder
18.0	Is the draft response provided complete? If yes, go to 19.0 If no, go to 18.1	Approver
18.1	Request clarifications, additions and/or redrafting. Go back to 12.0	Approver
19.0	Provide quality review feedback on the draft response proposal. Go to 20.0	Approver
20.0	Update the draft response following quality review feedback Go to 21.0	Responder
21.0	Respond directly to the requester using AskEMA or post if there is no e-mail address. Copy the response in the commnets box so that the response is searchable and resolve the query. *End of Procedure*	Responder

10. Records

REQUESTS

All RFIs are logged electronically in AskEMA.

REPLIES

Electronic copies of sent replies are automatically filed electronically in AskEMA or manually uploaded if sent by post.

TIME SPENT

Records of time spent on RFIs are included in SAP-HR under chapter 17 – Transparency, Information and Communication - 50 Requests for information SAP (code 17.50) by all Agency staff members.

Triagers should record triaging time under code 17.51 (RFIs – triage)