



Deliverable 12.2: Quality Management Procedure for Guidance Development

Work Package 12

The project leading to this application has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 847593.



Document information

Project Acronym	EURAD
Project Title	European Joint Programme on Radioactive Waste Management
Project Type	European Joint Programme (EJP)
EC grant agreement No.	847593
Project starting / end date	1st June 2019 – 30 May 2024
Work Package No.	12
Work Package Title	Guidance
Work Package Acronym	WP12
Deliverable No.	12.2. revision 2.0
Deliverable Title	Quality Management Procedure for Guidance Development
Lead Beneficiary	SURAO
Contractual Delivery Date	M12
Actual Delivery Date	30.04.2023
Type	Report
Dissemination level	PU
Authors	J. Faltejsek (SÚRAO), P. Ormai, B. Nős (PURAM), P. Carbol (JRC), N. Železnik, I. Mele (EIMV), K.V. Fuzik (SSTC NRS), J. Mikšová (SÚRO),

To be cited as:

Faltejsek, J., Ormai, P., Nős, B., Carbol, P., Železnik, N., Mele, I. Fuzik, K. V., Mikšová, J. (2023): Quality Management Procedure for Guidance Development. Final version 2.0 as of 25.05.2023 of deliverable D12.2 of the HORIZON 2020 project EURAD. EC Grant agreement no: 847593.

Disclaimer

All information in this document is provided "as is" and no guarantee or warranty is given that the information is fit for any particular purpose. The user, therefore, uses the information at its sole risk and liability. For the avoidance of all doubts, the European Commission has no liability in respect of this document, which is merely representing the authors' view.

Acknowledgement

This document is a deliverable of the European Joint Programme on Radioactive Waste Management (EURAD). EURAD has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 847593.

Status of deliverable		
	By	Date
Delivered (Lead Beneficiary)	SÚRAO	30/04/2023
Verified (WP Leader)	Jiří Faltejsek	15/05/2023
Reviewed (Reviewers)	Balint Nos	15/05/2023
Approved (PMO)	Paul Carbol	25.5.2023
Submitted to EC (Coordinator)	ANDRA	26/05/2023

Executive Summary

Guidance documents are developed within Work Package 12 of the European Joint Programme on Radioactive Waste Management (EURAD).

High quality of the produced guidance is ensured through end-users involvement in the production process.

This Quality Management Procedure defines the general quality assurance criteria applied when authoring new guidance document within EURAD WP12.

Content

Executive Summary.....	4
List of Figures	6
1. Introduction	7
1.1 Objectives	7
2. Roles.....	7
2.1.1 Leading author.....	7
2.1.2 Contributors	7
2.1.3 End user representatives.....	7
2.1.4 Editorial board.....	7
2.1.5 WP12 team	7
2.1.6 EURAD coordinator (ANDRA)	7
3. Processes.....	7
3.1 Topic selection.....	7
3.2 Leading authors selection.....	8
3.3 Guide development methodology.....	9
3.4 Dissemination	9
References	10

List of Figures

Figure 1: The concepts of topic selection for the pilot guide and subsequent guides.	8
Figure 2: Scheme for guide production.	9

1. Introduction

This Quality Management Procedure outlines the quality principles and procedures to be taken into consideration while producing and updating guidance document in EURAD.

1.1 Objectives

This document describes roles and processes applied to the production of guidance documents within EURAD WP12. All activities must be in line with EURAD Quality Management Plan [1].

2. Roles

2.1.1 Leading author

It is an important quality criterion that the leading author possesses competence and have experience in the topic to author a guidance document. The leading author is responsible for the content and structure of the guide. They provide basic information and harmonize contributions from involved participants (Contributors) and have final decision on the end product.

2.1.2 Contributors

Contributors are co-authors with specific knowledge that is part of the topic. They can raise questions to be answered in the guidance document; provide examples of application; high-light specific needs based on their practical experience. Their contribution will be moderated by leading author(s).

2.1.3 End user representatives

Potential end-user experts should participate in the defining the scope of the guidance document, solve production issues and be involved in the review of produced guidance. Their participation is on a voluntary basis. They could raise any issue according to their needs.

2.1.4 Editorial board

The Editorial board (Board) is composed of independent experts. The Board consists of at least 3 members which are nominated from different groups of entities acting in radioactive waste management.

The Board member should have high reputation and long-term experience in the field of radioactive waste management.

The Board members comment drafts and reviews the guidance documents before their publication. This Editorial board review could be part of the final EURAD review process.

2.1.5 WP12 team

The WP12 team members take part in developing deliveries in roles described in sections 2.1.1, 2.1.2 or 2.1.3 depending on their experience in the particular topic. The team supports the authors in the writing process and administers the production.

2.1.6 EURAD coordinator (ANDRA)

ANDRA provides contractual support in case that external to EURAD experts are contracted to author the guide.

3. Processes

3.1 Topic selection

The procedure for pilot guide topic selection and subsequent guides is shown in Figure 1 and described in delivery D12.3 *Approved list of prioritized topics for further guidance documents and selection of one topic for the development of a pilot guide* [2]. Criteria's for prioritisation of guidance topics were

developed jointly by the EURAD PMO and WP12 team. A long and short list of pilot guide topics was proposed, discussed and finally approved by the General Assembly.

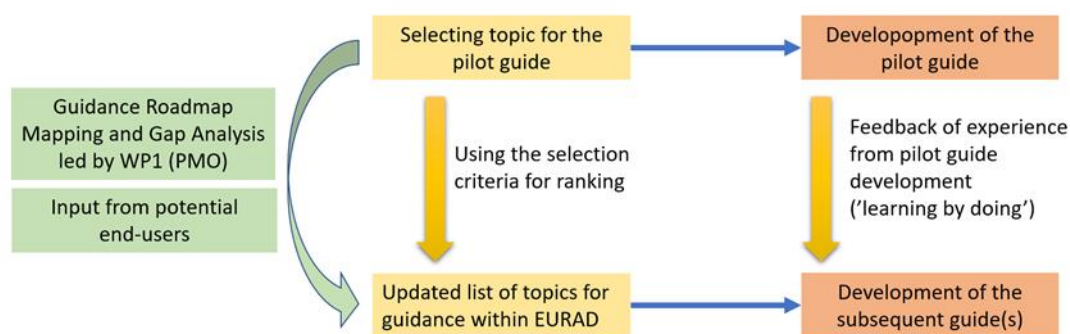


Figure 1: The concepts of topic selection for the pilot guide and subsequent guides.

The starting point for selection topics for subsequent guides was completion of a literature survey (Delivery D12.7 *Guidance and Guide-like documents on Geological Disposal of SNF, HLW and Long-lived Waste - Contribution to the EURAD Roadmap Gap Analyses*). This deliverable orients users to which knowledge exists (signposting) and what can be used for planning and implementing a radioactive waste disposal programme. Based on the literature survey it was concluded that although available technical documents and guidance are abundant, early-stage programmes or small inventory programmes often face the challenge of information overload and deciphering which sources of information are the most accurate and the most recent, thus the guidance should aim at providing concise references to orient the reader.

Using the literature survey and taking into account the potential topics previously considered for the pilot guide selection process, the WP12 team identified the list of 10 potential topics. A consultation process was carried out in which feedback from potential end-users, EURAD work package contributors and from the Editorial board were used to prioritise the guide topics.

Finally, a consultation with the Chief Scientific Officer (CSO) of EURAD was organised. It was identified that the common denominator of the majority of suggested topics was a requirements management. Jointly, the WP12 and the CSO developed a plan for the first guide - general guide on requirements management system (RMS). This guide will provide a framework (framework guide) for further specific guides and will cover the general role of requirements in the implementation of the geological disposal facility (or any other disposal facility) during its all implementation phases. After finalising the framework guide on RMS, some examples of RMS application to particular processes in a disposal programme implementation can be defined as topics for further guides (specific RMS guides) to be developed within EURAD.

The process is described in the delivery D12.5 *Updated list of prioritized topics for future guidance documents* [4].

3.2 Leading authors selection

The leading authors should have experience and competence for the development of particular guidance document. It is an important quality criterion, that the leading authors should have experiences and highly qualified competencies to the topic, the guide covers. They should be able to share their experience with EURAD beneficiaries (The intellectual property should be addressed).

The preferred option is to appoint the leading author within the WP12 team. In case that there does not exist that expertise inside WP12, the team will search in the other EURAD WPs or outside the EURAD

consortium (beneficiaries, end-users, stakeholders). Accessibility to experts can be limited by other factors such as budget, interest, availability and the experts time table.

3.3 Guide development methodology

The production of the guidance is based on end-users needs and is developed through interaction with them. The anticipated work consists of planning workshops, drafting the guidance documents based on the input from the end-users and updating the guide based on the feedback received during socialisation of the draft document. The updated scheme of guide production is shown in Fig. 2.

An important part of ensuring the quality of the guidance produced is understanding of the end user's expectations and how to meet them. Bringing end users into the guidance creation process is an essential part of improving the quality of the guidance. Gathering the needs and interacting with the end-users is achieved via workshops, questionnaire(s), sharing draft documents for commenting and through interactions in-between workshops among end-users and groups of end-users having similar questions and needs.

End-users with similar needs may be grouped and a rapporteur for each group is selected. He/She serves as a communication channel for each group during the guide production.

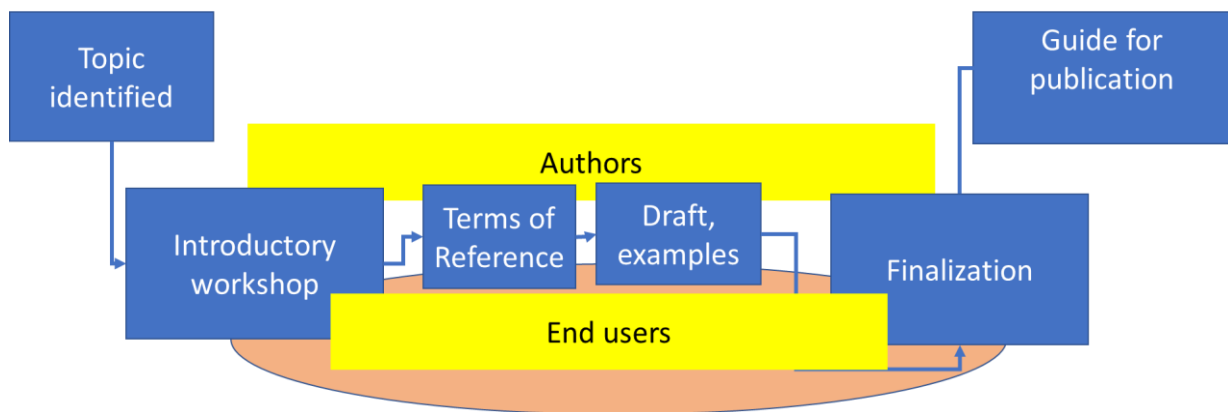


Figure 2: Scheme for guide production.

From the initial workshop presentations and subsequent discussion an initial draft is prepared for discussions and commenting during interactions with potential end-user representatives. Next step is incorporation of feedback comments and finalization of the guidance draft before its final review.

The final review is done by the WP12 team and the Editorial board. The finalised delivery with resolved comments from the review made by Editorial board members is then provided to Bureau for its final review according to EURAD's QA procedure.

3.4 Dissemination

During the production process the end-users could be asked if a subsequent training would support the dissemination of the guide. Guidance training material could be prepared based on the approved deliverable and training could be prepared in cooperation with WP13. Other dissemination activities could be made through for example EURAD Lunch & Learn sessions, introduction in the IAEA INIS and inserting the guidance into the EURAD Roadmap Wiki (WP11).

References

- [1] EURAD Quality Management Plan. Updated version as of 01.10.2021 of deliverable D1.5 of the HORIZON 2020 project EURAD. EC Grant agreement no: 847593. <https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5d3a8b68d&appId=PPGMS>
- [2] (2021) Approved list of prioritized topics for further guidance documents and selection of one topic for the development of a pilot guide D12.3 of the HORIZON 2020 project EURAD. EC Grant agreement no: 847593. https://www.ejp-eurad.eu/sites/default/files/2021-11/EURAD%20-%20D12.3_%20Approved%20list%20of%20prioritized%20topics.pdf
- [3] (2022) P. Ormai et al.: Guidance and Guide-like documents on Geological Disposal of SNF, HLW and Long-lived Waste – Contribution to the EURAD Roadmap Gap Analyses. Final version as of 02/11/2022 of deliverable D12.7 of the HORIZON 2020 programme EURAD. EC Grant agreement no: 847593. <https://www.ejp-eurad.eu/sites/default/files/2022-11/EURAD%20-%20D12.7%20Contribution%20to%20the%20EURAD%20Roadmap%20Gap%20Analyses%20-%20Guidance%20and%20guide-like%20documents.pdf>
- [4] (2022) B. Nős et al.: Updated list of prioritized topics for future guidance documents, Deliverable D12.5 of the HORIZON 2020 programme EURAD. EC Grant agreement no: 847593. <https://www.ejp-eurad.eu/sites/default/files/2022-11/EURAD%20-%20D12.5%20Updated%20list%20of%20prioritized%20topics%20for%20guidance%20documents.pdf>