**HSSC13-05.5B**

## Paper for Consideration by HSCC

**Report on the application of some ISO 9001 Principles in the development of S-101 PS**

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| ***Submitted by:*** | HSSC vice chair, DQWG chair, Sweden (SMA) |
| ***Executive Summary:*** | This paper presents the process scheme and description of the development of S-101 Product Specification, according to ISO 9001 principles. Some recommendations are proposed to carry on the experiment of applying ISO 9001 for process management. |
| ***Related Documents:*** | - |
| ***Appendices***  ***Related Projects:*** | 1-Process scheme of S-101 Product Specification (PS)  2-Process description of S-101 PS (so called “Routine”)  3-Manage risks and opportunities of S-101 PS  HSCC; S-100; S-101; DQWG. |

## Introduction / Background

## The Assembly, following the approved voting procedure by correspondence as reported in ACL 19/2020, confirmed the adoption of the effective implementation of the Revised Strategic Plan keeping in mind to apply the principles of ISO 9001 as the main theme of supervision and control of the Council until Assembly 3 (A-3).

## Following the adoption of the Revised Strategic Plan by A-2, the Council noted that the effective implementation of the Strategic Plan 2021-2026 is to be considered as the main theme of supervision and control of the Council until A-3, keeping in mind to apply the principles of ISO 9001 (deadline A-3) – see decision and action C4/36. The council agreed to experiment the application of the ISO 9001 principles on a couple of Strategic Plan targets (one per Committee to be proposed).

## From the 2020 chair group meeting, it has been proposed to make a process description for the development of S-101 towards the operational edition 2.0.0, under DQWG, keeping in mind that the approach could be extended for future development of PS. The purpose is not to achieve the full ISO 9001 certification.

## Analysis/Discussion

1. 3 meetings held during the period :

20/01/21 - Hans Engberg (SMA), Patrik Nilsson (SMA), Nathalie Leidinger (HSSC Vice Chair)

27/01/21 - Hans Engberg (SMA), Patrik Nilsson (SMA), Rogier Broekman (DQWG Chair),

Nathalie Leidinger (HSSC Vice Chair)

5/03/21 - Hans Engberg (SMA), Patrik Nilsson (SMA), Rogier Broekman (DQWG Chair), Julia Powell (S100 WG Chair) – Thomas Richadson (S101 PT Chair), Nathalie Leidinger (HSSC Vice Chair)

1. Achievements are presented in Appendices :
   1. Process scheme of S-101 Product Specification
   2. Process description of S-101 PS (so called “Routine”)
   3. Manage risks and opportunities of S-101 PS
2. During these meetings, important concerns have been raised :
   * S-100 interoperability is complex, it demands harmonization between PSs and so interaction between WGs which in turn need harmonization between timeframes.
   * External factors have great impact on the process : S-100 Ed 5.0.0, software and test data sets availabilities, regulations, …
   * Monitor the critical path to Ed 2.0.0 of S-101 PS is the important challenge, to avoid scope creep.
3. All these concerns are process management concerns. Managing risks and opportunities should contribute to reach our objective. According to ISO, risks and opportunities have to be determined and addressed but there is no requirement for a formal documentation. We should ensure that we have a methodology in place to effectively identify and assess risks and opportunities, take actions (to reduce risk or seize opportunity) and monitor the effectiveness of these actions.
4. An active draft of S101 Value Added Roadmap is being developed under S-101 PT and it is envisaged that the Roadmap will include a Risk Register which logically supports the planned work to apply ISO 9001 principles.(from report of S-101 Project Team HSSC 13-5.1C). The document “Manage risks and opportunities of S-101” should help to develop the Risk Register of S-101 Value Added Roadmap.

## Conclusions

ISO 9001 principles should help to achieve the goals, not create new constraints. During the experiment performed the vision for the application of ISO9001 has been: “simple and useful”. The experiment shows a possible application. However, in order to consolidate the risk and opportunities document and to add pertinent milestones etc. for the S-101 PS development it is suggested to continue the experiment until the next HSSC-meeting.

## Recommendations

1. The “HSSC ISO 9001 cell” should remain active, at least until HSSC14.
2. A S-101 Project Control Officer (PCO) should be designated – preferably the vice-chair of S-101PT.  
   *The S-101 PCO should be in charge of controlling the progress of the development of S-101 PS to operational edition 2.0.0. Practically the officer reviews risks and opportunities, updates the GANTT diagram, and reports biannually.*
3. The “HSSC ISO 9001 cell” should be composed of the DQWG chair, 1-2 experts of ISO 9001, S-101 Project Control Officer (PCO) and HSSC vice chair.
4. The vice chair of HSSC should be designated HSSC PCO of the activities related to the application of ISO 9001 principles.
5. The “HSSC ISO 9001 cell” should define a performance indicator of S-101 PS development, consisting on pertinent milestones, built on a GANTT diagram highlighting the critical path. (See “Manage risks and opportunities of S-101 PS” document) – to be presented on HSSC14.

## Justification and Impacts

These recommendations address the requirement of experiment the application of ISO 9001 principles on a Strategic Plan target for HSSC.

## Action Required of HSCC

The HSCC is invited to:

a. **Note** this paper;

b. **Discuss** proposed recommendations;

c. **Endorse** the principle of continuing the experiment with the setup of a loose organisation: the “HSSC ISO 9001 cell” and “Project Control Officers”;

d. **Task** the S-101 PT to take recommended actions ;

e. **Initiate** any actions as considered as necessary.