MB/42/2013 final
Helsinki, 26.09.2013

# Integrated Quality Management System

Meeting of the Management Board 26-27 September 2013

| | |
|---|---|
| **Item** | 9 |
| **Action** | For information |
| **Status** | Final - public |

## Action requested

The Management Board is invited to take note of the information provided in this annual progress report.

## Background

The Agency implements the Integrated Quality Management System (IQMS) in accordance with the relevant Multi-Annual Work Programme[1,3] and Annual Work Programme[2,4]. The IQMS strongly supports the Agency's strategic aims[3], in particular by providing means to ensure the effectiveness and efficiency of the Agency's processes.

In accordance with the Annual Work Programme 2012[4], the Agency established a Roadmap leading towards ISO 9001 Certification (see annex). The Roadmap covers the period 2012-2014. It guides the IQMS implementation work and prepares the Agency for the ISO 9001 certification, as planned in the Multiannual Work Programme 2013-2015.

The ISO 9001 Roadmap was confirmed by the Quality Steering Committee[5] and subsequently presented to the Management Board in the annual progress report 2012[6].

The main achievements made in the course of 2012 were summarised in the General Report 2012[7].

This present progress report informs the Management Board about the main activities undertaken since September 2012, and outlines the status and next steps of the ISO 9001 Roadmap implementation.

## Matters for consideration

### IQMS realisation – main activities since September 2012

**1.** The development of the IQMS is an on-going activity involving all Directorates of the Agency. The approach to integrated quality management paves the way towards the realisation of a modern integrated management system. The compliance with the ISO

[1] ECHA Multi-Annual Work Programme 2012-2014, 21.06.2011, MB/25/2011 final
[2] ECHA Work Programme 2013, 27.09.2012, MB/35/2012 final
[3] ECHA Multi-Annual Work Programme 2013-2015, 21.06.2012, MB/19/2012
[4] ECHA Work Programme 2012, 15.12.2011, MB/56/2011 final
[5] Quality Steering Committee meeting on 21 June 2012
[6] Integrated Quality Management System, MB/45/2012, Meeting of the Management Board, 27-28 September 2012
[7] General Report 2012, ECHA-13-A-03-EN, 22.03.2013, MB/06/2013 final

9001:2008 requirements facilitates the successive incorporation of elements that are relevant for environmental management, occupational health & safety, business continuity, social responsibility, as well as security and information security.

**2.** The Agency's Activity and Process Structure[8] - established in 2011 as a common basis for various purposes, such as resource planning, work planning and cost accounting – was further refined to reflect the evolving process system. The integration of processes stemming from the Agency's new activities under the Biocides and PIC regulations has started.

**3.** The individual process teams continued with the development and description of the processes, paying particular attention to their effectiveness and the efficient functioning of the overall process system.

The REACH and CLP processes were further optimised. Following the legislative timeline, the work concentrated on the Applications for Authorisation and the Substance Evaluation processes. The operational processes, defined in the past years, were reviewed with regard to accommodating the upcoming needs resulting from the Agency's tasks under the Biocides regulation.

**4.** The description of the management processes was complemented with procedures related to the internal management of the Agency and the management of the relations with Stakeholders, including their engagement, the assessment of their needs and expectations as well as their satisfaction.

The current focus is on the planning and reporting processes, in particular the deployment of objectives from the strategic to the operational and individual levels, including the definition of suitable indicators to measure their achievement. A refinement of the procedures and mechanisms for reporting to and review by Management is in progress.

**5.** In the Corporate Services area, the work started in 2012 was continued. These processes are also relevant for the intended incorporation of environmental management[9] into the IQMS framework.

The management of fixed assets was strengthened through a dedicated policy and the development of the relevant crosscutting structures and procedures.

The on-going analysis of the procurement and contract management processes and the related procedures aims at streamlining the processes and enhancing the related Internal Control System.

The ICT infrastructure continues to grow. A full review of the process architecture was undertaken. The existing procedures related to the management of IT projects and services were analysed and relevant documentation was elaborated or planned.

**6.** The handling of nonconforming work and complaints was harmonised at Agency level. The internal structures and means for the identification and appropriate follow-up of complaints were developed in the framework of the nonconformity management procedure.

As a consequence of the unsuccessful procurement of specific quality management software, an interim solution for automated NC-CAPA[10] workflows was put in place in 2012. The development of bespoke software is in progress.

---

[8] LIS-0009 Activity and Process Structure

[9] ISO 14001 Environmental Management Systems, EU Eco-Management and Audit Scheme (EMAS), or equivalent

The individual process teams collected improvement proposals and used the observed deviations and nonconforming work for the further development of the processes. About 85% of the main nonconformities recorded in 2012 were solved in the course of the year. The same percentage applies to the improvement proposals. The majority of the improvement actions, nearly 60%, targeted the process design. Other actions related to the technical enhancement of processes, the further development of competences and the fit-for-purpose documentation.

**7.** Annual plans for internal quality communications and training were established in 2012 and 2013. Capacity building continued through regular staff training, targeted information sessions for specific audiences and awareness raising in matters related to quality.

All Quality Assurance Officers received an in-depth training tailored to their specific role. Four training sessions were organised in the second half of 2012. The Quality Manager participates in Unit meetings and informs about the IQMS realisation and planned certification of the system. Specific training and information sessions about the ISO 9001 certification will be organised in the first half of 2014.

The Intranet IQMS pages were updated. An update and completion of the information published about the IQMS on ECHA's website is planned. On the occasion of the World Quality Day in November 2012, several internal communications emphasised the benefit that quality offers. The Agency's annual *Quality matters!* event was organised for all staff in February 2013. Similar events are planned for November 2013 and February 2014.

**8.** The revision of the IQMS documentation scheme resulted in a simplified and clearer structure. Process maps, depicting the interaction of processes, are available for certain Activities. The maps are complemented with Activity or process descriptions, were meaningful.

The Agency's Quality Manual is in preparation and will be effective as per January 2014. The new and revised IQMS documents reflect the progress made with the further development of the system components. A total of 313 IQMS documents[11] exist for 13 out of the 16 Activities.

The procedures that are expected to be of particular interest for external audiences are published on the ECHA website. Currently, 21 procedure documents inform about the Agency's work processes.[12]

**Plan-actual comparison of the ISO 9001 Roadmap implementation**

**1.** The Annual Work Programme 2013 indicates that the IQMS shall fulfil the requirements of the ISO 9001:2008 standard to 80% by the end of 2013.

The second IQMS assessment, performed in Q4-2012, included a gap analysis against the ISO 9001 requirements, and identified parts of the IQMS that were not sufficiently covered by the continuing implementation activities. Based on the ensuing recommendations, the process teams focused their implementation work in the first half of 2013 on ensuring

- the completeness and integration of the continual improvement cycle (plan-do-check-act) at Activity and process level;

[10] Management of Nonconformities, Corrective Action and Preventive Action
[11] Status as per 22 August 2013; For comparison: 218 documents as per 10 September 2012, 130 documents as per 6 September 2011; 56 documents as per 20 September 2010
[12] Status as per 05 September 2013; For comparison: 5 procedures as per September 2011, 10 procedures as per September 2012.

- the purposefulness of the existing IQMS documentation;
- the availability of records to prove the functioning of the cycle in accordance with the existing IQMS documentation.

The progress monitoring at mid-term of the Roadmap implementation, estimates the fulfilment of the ISO 9001:2008 requirements at about 65%. Specific action plans will guide the process teams in the second half of the year towards the achievement of the targeted 80% standard compliance.

**2.** According to the Roadmap, the fundamental elements of the IQMS should be in place by end of June 2013. Some of the projected activities are behind schedule. The delay mainly concerns the realisation of the harmonised process system, the comprehensive Agency-wide nonconformity and complaints management, and the alignment of internal IQMS audits with the Agency's regular internal control audits. Relevant activities are in progress.

The Roadmap foresees the continued development of processes, and hence the time plan is respected. A review of the implementation practice showed potential for enhancement and efficiency gains through a higher degree of standardisation and an alignment of individual solutions in certain areas. The combination of several projected activities with the day-to-day work will facilitate the wider involvement of staff and foster the preparedness for the ISO 9001 certification exercise.

**3.** The IQMS assessment was carried out according to plan. The IAC and IAS audits relate to relevant system elements, such as external communications, Stakeholders, documentation and record management, provided further information. Dedicated internal IQMS audits will start in Q4-2013.

**4.** The regular reporting to and review by ECHA Management ensures that the implementation activities are carried out according to plan. Management reviewed the overall IQMS implementation in February 2013[13]. The Quality Steering Committee follows the progress made with the implementation activities on an annual basis[14].

**5.** The action planning and prioritisation of activities in the upcoming months aims at preventing delays with the overall Roadmap implementation. At present, it can be concluded that the achievement of the ISO 9001 compliance within the timeline of the Roadmap is feasible, provided the projected actions will be carried out according to plan.

**6.** Although the overall IQMS work is progressing and support is provided to process teams through Consultancy services contracted under a specific Framework Contract, it has to be noted that resource constraints continue to be a matter of concern.

**ISO 9001 Certification**

**1.** The Multi-Annual Work Programme 2013-2015 indicates that the Agency intends to obtain the ISO 9001 Certification of its Integrated Quality Management System by the end of 2015.

**2.** The Roadmap foresees the organisation of a pre-certification audit in Q2-2014 and envisages the actual certification audit in Q4-2014. The pre-certification audit will be carried out by the independent Certification Body. The audit will provide, from the point of view of the Certification Body, an indication about the Agency's preparedness for the actual certification exercise. Depending on the outcome of the pre-certification audit, Management will decide on the appropriate date for the ISO 9001 certification.

[13] Management Review, 6 February 2013
[14] Meeting of the Quality Steering Committee, 26 August 2013

**3.** The scope of the ISO 9001 certification was discussed by the Quality Steering Committee. Although it is possible to limit the scope to certain operational processes for the Agency's initial certification, and extend it subsequently, for example at surveillance or recertification audits, it was recommended to aim at the certification of the processes related to the Agency's tasks under the REACH and CLP regulations.

## Attachment:

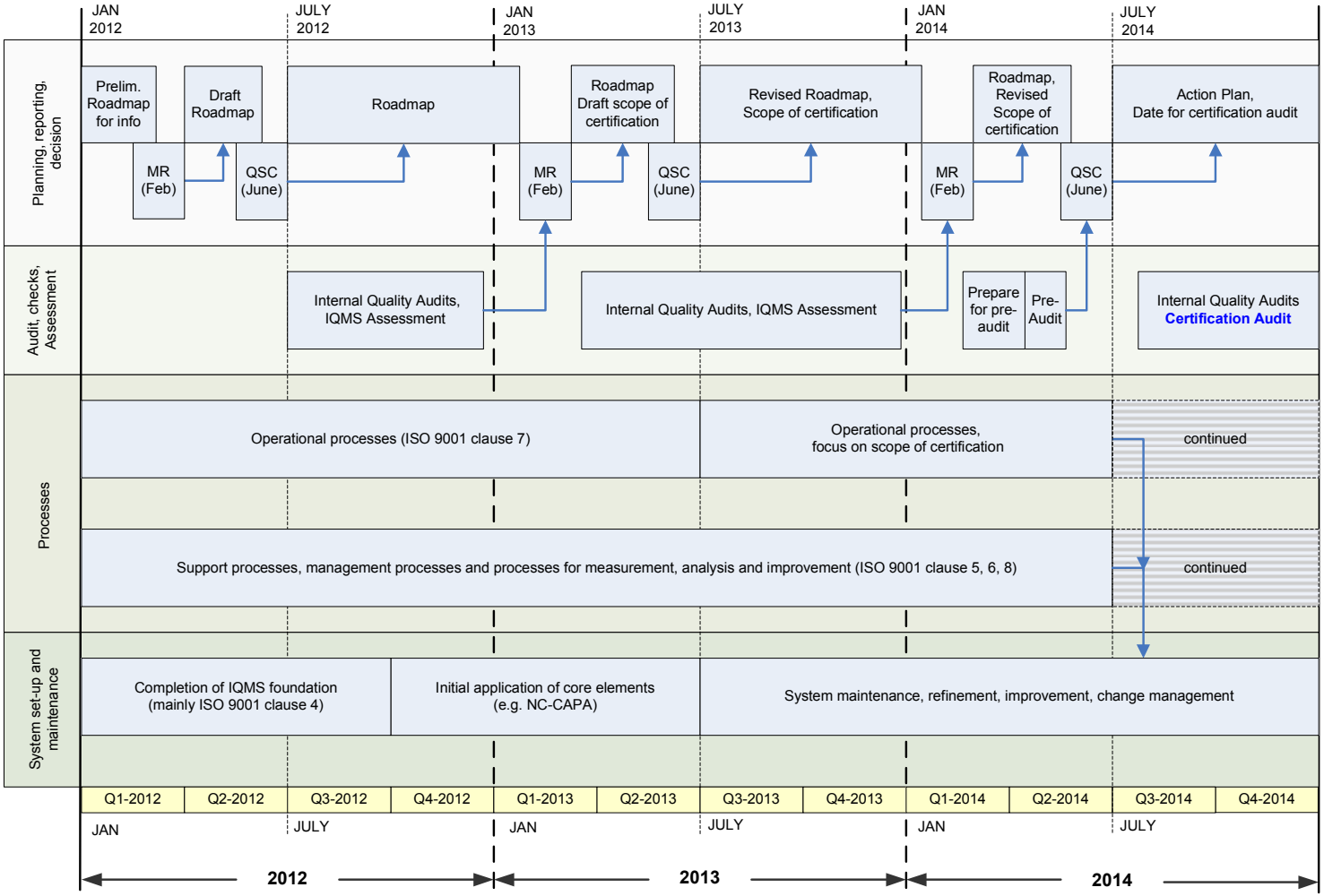
Roadmap leading towards ISO 9001 certification

MB/42/2013 final
Helsinki, 26.09.2013

**Annex:**

**Roadmap leading towards ISO 9001 certification**

Roadmap leading towards ISO 9001 Certification (period covered: 2012 to 2014)




QSC – Quality Steering Committee
MR – Management Review
NC-CAPA – Nonconformities, corrective and preventive action

Approved version / Quality Steering Committee on 21 June 2012