
INTEGRA

Integrated External and Internal Exposure Modelling Platform (INTEGRA)

**B11 - Realistic estimation of exposure to substances from multiple sources
(CEFIC Long-range Research Initiative funded project)**

TOTAL QUALITY MANAGEMENT PLAN

Due date of delivery: 31/04/2013

Actual submission date: 31/04/2013

Start date of the project: 01/01/2013

Duration: 27 Months

Lead contractor organisation name for this deliverable: **CERTH**

Dissemination Level		
PU	Public	
PP	Restricted to other programme participants	X
RE	Restricted to a group specified by the consortium	
CO	Confidential, only for members of the consortium	

Document Information

Document Name TOTAL QUALITY MANAGEMENT PLAN
ID -
Revision Version 1
Revision Date 28/03/2013
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Approvals

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Documents history

Revision	Date	Modification	Author
Version 0	22/3/2013	1 st draft	D.A. Sarigiannis
Version 1	31/4/2013	Final editing	D.A. Sarigiannis

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1 INTRODUCTION

INTEGRA has partners of different disciplines and scientific backgrounds, aiming at bringing together different knowledge sources and information processing tools to deliver an all-around comprehensive instrument for assessing realistic estimation of exposure (external and internal) to substances from multiple sources related to the life-cycle of chemical in consumer goods. A set of guidelines and management assistance documents will be drafted in order to assure the innovative character and quality of the on-going research while respecting the imposed time constraints. The scope of this quality management plan is to provide the basis of a robust monitoring and control framework that will serve as aid for the project manager, as well as the managers of the individual work packages. The methodology suggested follows the guiding principles of total quality management, encompassing not only quality management (control and assurance) of output, but also quality of the management processes and communication flow amongst the consortium partners. The guidelines below follow the scheme of (a) identification of the potential problem and (b) suggestion of specific measures to both prevent and redress the eventual problems.

2 PROBLEM SEMIOLOGY

Common problems encountered are:

- Unsatisfactory level of work co-ordination.
- No integrated collaboration in development work.
- Bilateral collaborations among the involved partners.
- Outstanding problems and bad allocation of resources.
- Work packages not meeting the scientific quality standards set during the initial stages of the project.
- Delayed delivery of work packages resulting to suboptimal implementation of the on-going results.
- Suboptimal dissemination of findings and results among the interested scientific and business groups.
- Violation of time constraints.

Response to these potential problems is given below.

2.1 Assuring Work Co-ordination

Work co-ordination among the research partners is critical in assuring the quality and innovative character of the on-going research as well as of the final product. Suboptimal work co-ordination could lead to:

- Work Overlapping.
- Time delays.
- Erroneous strategic decisions due to lack of dissemination of results among the involved partners.

Measures that could assure adequate co-ordination among the research partners are:

- Dissemination of evaluation results through the extensive and frequent use of a dedicated dropbox.
- Safeguards ensuring impartiality and independence.
- Evaluation planning.
- Useful and credible results.
- Sufficiently extensive and frequent evaluations of the on-going research results from goal managers.
- Assuring participation of the interested research partners in brainstorm meetings.
- Transparency regarding on-going findings among the involved research partners.

- Uninterruptible supply of information regarding the progress of a particular work package to the work package manager.
- Uninterruptible supply of information from the work package managers to the project manager.
- Use of help documents to pinpoint time bottlenecks and deficiencies of the on-going work.

2.2 Integrated collaboration in development work

Collaboration in development work is a prime requisite for keeping up with the on-going state of the art and optimal coupling of the knowledge gained from different scientific disciplines. Both intra and inter group collaboration should be encouraged in effort to maximize efficiency and reduce time lags. Work package managers in collaboration with the project manager are encouraged to create an information network to readily identify the sub-groups that could benefit the most from cooperation during a particular stage of the on-going project. Modifications with regard to the established links among the different work groups should be encouraged in an effort to optimize group performance. The proposed guidelines for assuring collaboration in development work are:

- Uninterruptible supply of information from the project manager to the work package managers.
- Establishment of work links.
- Establishment of a common format for information exchange and result dissemination.

2.3 Preventing non-coordinated collaboration

Although the establishment of bilateral collaborations in a multidisciplinary work group seems appealing and could in some cases accelerate the performance on a specific research area, if not well coordinated it may have a deteriorating effect on the overall performance of the work group and cancels all potential benefits of collaboration. Potential problems that usually arise in multidisciplinary groups from excessive bilateral and oligolateral collaborations are:

- Suboptimal use of the gained knowledge.
- Communication deficiency among the involved work groups.
- Deviation from the originally set requisites.

Measures preventing these deteriorating effects are:

- The establishment of collaborations among work groups only through the common agreement of the project manager and the responsible work package managers.
- Establishing a precise set of objectives that should be met through collaboration, while assigning clear responsibilities to the partners concerned.
- Establishing strict time constraints with regard to intergroup collaboration. This is particularly important for the successful and timely conclusion of tasks requiring collaboration between different research groups (and, especially when interaction between software developers / data providers

and end-users is necessary for successful completion of the task). Timely information exchange is necessary to ensure the uninterrupted workflow throughout project execution.

- Reducing clutter with regard to information exchange.
- Establishment of a common format for information exchange and result dissemination.
- Uninterruptible supply of information from the involved work package managers to the project manager with regard to the progress of collaborative actions.

2.4 Solving outstanding problems - avoiding bad allocation of resources

Problems with regard to the requirements set and in particular with the development of the scientific framework and its implementation can be solved as follows:

- The establishment of bilateral or oligolateral (or in general, non-coordinated) collaborations under the strict supervision of the involved work package managers as well as the project manager. The aim of this particular collaboration is the provision of a solution to a particular problem.
- Accurate result dissemination from the work package manager to the interested researchers of the on-going information regarding their area of involvement.
- Monitoring the state of the art in the involved scientific areas and taking advantage of the on-going knowledge produced.
- Creating a set of rules and guidelines in order to:
 - Identify the extent of a potential problem, its impact on the smooth progress of the on-going work of the specific group and its implications with regard to the group.
 - Anticipating the creation of potential problems through rigorous monitoring of project progress and implementing a bottom-up analysis in order to identify possible areas (in research, demonstration or implementation of the INTEGR approach) where such problems could arise.

Bad allocation of resources, both scientific and economic results to loss of potential gains as well as reduces the quality of the work done. Optimal allocation of resources can be assured if:

- The set of requirements of a particular task are clearly drawn.
- The work package managers are closely monitoring the on-going research.

2.5 Assuring Quality of the Work-Package Deliverables

Quality verification of the deliverables is one of the most prominent targets of the project, in particular given the very heavy user-orientation of INTEGR. Deliverables not meeting the quality criteria could result in:

- Final report of sub-standard quality.
- Sub-optimal use of the available scientific resources.

- Increase of some partners' workload in an effort to achieve the minimum success criteria.
- Obstacles to collaboration among the partners.

Output of all work packages must adhere to the following guidelines to meet the project standards:

- An acceptable work package result must be of value and interest to the collaborating partners. It must be an original review of past practice, present information of current interest, or probe new fields of its research areas. It should be a well-focused product that contributes to the planning, analysis and design of the particular task. Authors should comply with the following:
 - An author's central obligation is to present a concise account of the research, work, or project completed, together with an objective discussion of its significance.
 - A submitted work-package shall contain detail and reference to public sources of information sufficient to permit the involved partners to repeat the work or otherwise verify its accuracy.
 - An author shall cite and give appropriate attribution to those publications, which are influential in determining the nature of the reported work in a manner that will be sufficient to guide the reader quickly to earlier work essential to understanding the present work. Information obtained by an author privately, from conversation, correspondence, or discussion with the involved scientific partners or third parties shall not be used or reported in the author's work without explicit permission from the persons from whom the information was obtained. Information obtained in the course of confidential services, such as refereeing manuscripts or grant applications, shall be treated in the same confidential manner.
 - Fragmentation of work packages shall be avoided.
 - To protect the integrity of authorship, only persons who have significantly contributed to the research or project and manuscript preparation shall be listed as co-authors.
- The work package output must be consistent and concise. It must not contain speculative opinion, although it can use scientific evidence to challenge current concepts or propose new ideas that will encourage progress and discussion.
- The manuscript must be free of evident commercial or private interest, but must neither obscure proper names when they are required. The material must not be readily available elsewhere.
- The guidelines of work package (task) leaders with regard to the quality of the submitted work are summarized as follows:
 - A work package (task) leader shall objectively judge the quality of a manuscript on its own merit and shall respect the intellectual independence of the author.
 - Unpublished information, arguments, or interpretations contained in a submitted manuscript are confidential and shall not be disseminated elsewhere except with the

- consent of the project manager and with appropriate reference to the project and the CEFIC-LRI programme.
- A work package (task) manager shall treat the research work as a confidential document and shall neither disclose or discuss it with others except, as necessary, with persons from whom specific advice may be sought; in that event, the identities of those consulted shall be a priori disclosed to the project manager and his/her written consent is requested.
 - Work package (task) managers shall explain and support judgments adequately so that the editor and author(s) of the work package deliverables may understand the bases for their comments and proceed to modifications (if any). Any statement that an observation, derivation, or argument has been previously reported shall be accompanied by the relevant citation.
 - A work package (task) manager is responsible against the project manager with regard to plagiarism.
- Moreover the project manager should adhere to the following guidelines in order to assure the quality of the research done:
 - The primary responsibility of the project manager is to establish and maintain high standards of technical and professional quality with regard to the objectives set for the project. Criteria of quality are originality of approach, concept and/or application; scientific robustness; and relevance.
 - The project Quality Officer shall give unbiased consideration to all manuscripts offered for publication and shall judge each on its merits without regard to any personal relationship or familiarity with the author(s).
 - The project manager shall disclose no information about a work under consideration to anyone other than those from whom professional advice regarding the publication of the manuscript is sought. Reviewing from external auditors (the project monitoring team and the scientific advisory board) should be performed in a regular basis (i.e. project milestones).
 - The project manager shall avoid conflicts of interest and/or the appearance thereof. The project manager shall not send a manuscript to external auditors who are known to have personal bias in favor of or against the author(s) or the subject matter of that work.
 - Unpublished information, arguments, or interpretations contained in a submitted manuscript are confidential and shall not be used in the research of third parties, or otherwise disseminated except with the consent of the author(s), work package manager, project manager and the EC and with appropriate attribution.
 - The project manager is held responsible for assuring confidentiality of the work deployed in the local intranet. Access to the private domain of the local intranet should be

continuously monitored. The project manager should also be responsible for the scientific work available to public.

The Quality Assurance plan of the project includes:

- (a) the requirement to define clear specifications for each project deliverable.
- (b) the requirement to provide definitions of quality standards to be met by each deliverable (according to the ISO 9001 standards on quality systems – model for quality assurance in design, development, production, installation and servicing).
- (c) identification of the mechanisms for controlling the changes in project specifications eventually needed.

Table 1: Specifications and quality standards of key project deliverables

Deliverables list	Technical specifications / quality standards
Various technical reports	All the technical reports of the project will need to follow the guidelines expressed in detail in the chapter on quality assurance of project deliverables (in particular with regard to technical documentation and scientific benchmarking of the project findings)
Project presentation	The project presentation will need to communicate to the laymen users and interested public the salient scientific information regarding the INTEGRA methodology, exemplify its potential use and provide adequate contact information. Quality of information needs to be validated through combined acceptance from both the scientific and end-user partners in the consortium.
Dissemination/use plan	The plan for dissemination and use of the project results will follow the guidelines provided by project technical annex and agreement by CEFIC. The validity of the information provided by all partners will be verified by the signature of the authorized person in each of the partner organizations.
INTEGRA computational platform and database	The main INTEGRA computational platform will need to comply with full transferability and portability requirements, which will have to be determined in close collaboration between the INTEGRA team and end-users and in particular the CEFIC-LRI monitoring team.
Edited annual report	All annual reports and other standard contractual requirements for corporate reporting will follow the quality standards for reporting and project documentation outlined above.

In addition to the above, quality assurance in the project is based on the use of historical experience in chemical exposure and risk analysis and in the development of information systems for chemical risk management accumulated in the project partnership. Highly qualified resources included technical means and personnel will be used to assure the good quality of the project output. Impartial design reviews, involving potential stakeholders and end-users will be an additional element assuring that the final product design specifications meet the end-user requirements throughout the various project phases. Finally, configuration management will be used to ensure that the final product (INTEGRA methodology and computational platform) reflects the evolving needs of end-users and incorporates the current best understanding of the methods involved in aggregate exposure assessment.

The key deliverables will be grouped into basic configuration items, so that they can be individually documented and placed under change control. At the end of each project phase, the movement of configuration items through the project life cycle will be formally reviewed to check that specifications are up-to-date, complete (with all documentation necessary) and agreed upon by the consortium. A configuration baseline will be set up at the onset of the project and it will be revised periodically to reflect the current status of the project. The evolution of the configuration baseline will provide the configuration control mechanism necessary to ensure that changes find general agreement and meet the end-users needs at all stages of the project. With regard to quality control, appropriate statistical techniques will be used for the continuous monitoring of the total project quality (responsibility of CERTH acting as project coordinator).

2.6 Assuring transparency regarding on-going findings within the INTEGRA team

Transparency with regard to on-going research can be assured with the good use of the developed intranet and Internet web site. Research work should be readily reviewed by the work package manager, project quality officer and project manager and then published as soon as possible to the local intranet. Intranet meetings should be scheduled regularly in an effort to increase the impact of information dissemination. The work package managers are responsible for keeping their researchers up to date with regard to the work published in the local net. Moreover the project manager should inform the work package managers about related material as well as any time delays as soon as the material under examination meets the criteria set in the previous paragraph.

2.7 Violation of Time Constraints

Time constraints should be respected. Temporal violations with regard to the delivery of the specific package should be accepted only under the condition that all measures in order to avoid violating these constraints are taken. Responsibility for meeting time limits/targets traverses the project management structure through a series of sub-delegations. Scientists are held responsible to the work package leaders whereas the latter are responsible to the project manager for honoring time constraints. The project manager is responsible to CEFIC and the project monitoring team with regard to deadlines. The project manager should continuously monitor the following:

- The on-going progress of the project.
- The creation of bottlenecks.

- The temporal evolution of project critical packages.

Work package managers should continuously do the following:

- Monitor the on-going progress of their specific work package.
- Identify bottlenecks and possible time delays with regard to the development of either the software or hardware or the relating theoretical background of the package that are held responsible.
- Inform the project manager for possible delays.
- Produce weekly and monthly reports with regard to the progress of the work done.
- Allocate scientific resources in a way to maximize the performance of their work groups.

The project manager should be in regular contact with the project monitoring team designated by CEFIC with regard to the progress of the project. In the case of critical time delays, in collaboration with the work package leaders, measures should be proposed in an effort to circumvent potential problems. These measures could be:

- Re-organization and re-deployment of the project time plan. All affected partners should be informed with regard to the delay. It is of particular importance to attempt to minimize resulting project execution delays especially in the case of tasks comprising the critical path of the project.
- Re-allocation of scientific resources.
- Although not recommended, request of extension of time to CEFIC. The project manager in this case is obliged to present a detailed report with the difficulties and drawbacks that led to violation of the time constraints, the measures taken during the project in order to overcome these problems as well as the partners responsible for the time delays.

3 CONCLUSIVE REMARKS

Specific quality management requirements for the INTEGRA project arise from its main scope; linking a variety of different data types (environmental and biomonitoring) and models. Considering that data will cover a very wide chemical space, data from different sources will need to be exploited for the methodology development and validation. However, prior to the use for INTEGRA purposes, this data has to be explicitly evaluated by the INTEGRA research team so as to meet specific data quality criteria such as:

- Appropriateness: INTEGRA proposes a very dynamic integrating framework for linking external and internal exposure. In order to compile a data-rich dataset, data from different spatial and temporal scales has to be utilized for validation purposes and this will be more evident for internal exposure validation.
- Completeness: previous experience from B5 – TAGS (CEFIC LRI) project on data gaps identification and filling will be the driving force for improving the quality of data in terms of completeness. However, the overall INTEGRA methodology will provide an overall comprehensive methodology for handling exposure and risk characterization assessment for data-poor chemicals.
- Accuracy: Data should be free from material mistakes, errors and omissions. Data is considered to be accurate if the recording of information is adequate, performed in a timely manner and is kept consistent over time.

In terms of overall management quality, we need to underline that all partners have an excellent track record in interdisciplinary research at the International and European level. Each work package is led by a researcher at the top of their specific scientific discipline. This ensures that problems will be solved efficiently at an early stage. Several measures have been taken to prevent foreseeable problems from occurring. Moreover the consortium carries a long experience from previous and ongoing related CEFIC-LRI projects; the latter ensures that progress of work will move fast towards CEFIC-LRI scientific objectives, allowing the time needed for extensive quality control of the scientific outcomes and the corresponding deliverables