# **Quality System Procedure**

info@c-bq.com

www.c-bg.com

QSP 8.3

Subject: Design and Development

- 1.0 Purpose
- 2.0 **Scope**
- 3.0 Responsibility and Authority
- 4.0 <u>Design and Development Procedure</u>
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- 5.1. Criteria of 'Design and development' Process
- 5.2 Addressing the risks and opportunities of the 'Design and development' process
- 6.0 <u>Documented information of 'Design and development'</u>
  Process
- 7.0 Revision History

# Addendum 1

Typical product design and development stages

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QSP

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## 4.0 Design and Development Procedure

#### 4.1 General

'Design and Development' Process model is displayed on Fig. 1.

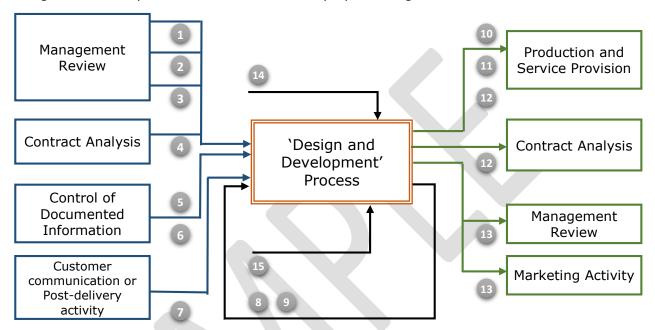


Fig.1 'Design and Development' Process Model

## 'Design and Development' Process Model Flows

- Development request
- Decisions on opportunities for improvement
- Decisions on the needs for change, including resources
- 4 Functional requirements and indicators
- Statutory and regulatory requirements
- Standards and regulations, the requirements of which the Organization complies to
- 7 Proposals to improve the product (improve service provision methodology)
- The data acquired from the design and development work completed earlier
- Potential consequences of failure due to the characteristics of products and services

Date



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- Characteristics of services, that are essential for their purpose and their safe and proper use
- Monitoring and measuring requirements
- Acceptance criteria
- Information about new developments
- QSP 8.3 'Design and Development'
  - Technical director and project managers
- Personal computers
  - Company server, software

## 4.2 Design and Development inputs include

 Development request – is issued by the Coordinating council based on strategic purposes, the analysis of market trends, analysis of stakeholder interests, including customer communication. The form of development request is an excerpt from the 'Coordinating Council Protocol' with the develop request assignment.

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 ✓ Actions to Address Risks and Opportunities Procedure

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✓ <u>Control of Documented</u>

Information in ISO 9001:2015 Clauses

7.

✓ <u>ISO 9001:2015 Overview.</u> Presentation for Training



✓ <u>Comparative Analysis of ISO</u> **9001:2015** vs. ISO 9001:2 008 7.

✓ **QMS Transition Program** (to the New Version of ISO 9001:2015)

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