

## QA in the Hot Cell Laboratories at NRG-Petten

Gin-Lay Tjoa  
Klaas A. Duijves

Petten, 30 September 1999

K5071/99.28320/1

Paper to be presented at European Working Group "Hot Laboratories and Remote Handling"  
Plenary Meeting, 13-15 October 1999 at European Institute for Transuranium Elements -  
Karlsruhe, Germany

author : Gin-Lay Tjoa	K.A. Duijves	reviewed : J.P. Boogaard
<i>WLT</i>	<i>29/9/99</i>	<i>30/09/99</i>
15 page(s) MMI/GLT/NO	approved : B. van der Schaaf	<i>B/S</i>
i28320	<i>990930</i>	

© NRG 1999

Subject to agreement with the client, the information contained in this report may not be disclosed to any third party and NRG is not liable for any damage arising out of the use of such information.

## **Contents**

<b>List of tables</b>	<b>2</b>
<b>List of figures</b>	<b>2</b>
<b>1 Introduction</b>	<b>3</b>
<b>2 NRG management system</b>	<b>4</b>
2.1 General	4
2.2 Structure	4
<b>3 The Hot Cell Laboratories</b>	<b>6</b>
3.1 Documentation	6
3.2 Quality implementation	6
<b>4 Audits</b>	<b>8</b>
<b>5 Future</b>	<b>9</b>

### **List of tables**

table 1 Review of Resolved Reports after Implementation of Management System	10
--	----

### **List of figures**

figure 1 NRG Organisation	11
figure 2 Structure of Management System	12
figure 3 Document Structure of Management System	13
figure 4 Management Procedure "Project Management"	14
figure 5 Management Procedure "Maintenance of Equipment and Installations"	15

## 1 Introduction

NRG is a new company, founded at the end of 1998 after a merger of the nuclear departments of ECN and KEMA. Since the staff of NRG originates from the nuclear departments of both companies, NRG acquired more than 35 years of experience in the nuclear field. Amongst others, this includes experience in the operation of a wide range of nuclear facilities, such as:

- operation of the 45 MW High Flux Reactor of the European Commission for materials testing, (medical) isotope production and BNCT (Boron Neutron Capture Therapy);
- operation of the 30 kW Argonaut Low Flux Reactor for training and biological applications;
- operation of the Hot Cell Laboratories for materials testing and isotope separation;
- overall responsibility of a Molybdenum Production Facility;
- operation of a Decontamination and Waste Treatment Facility for both internal and external services.

Until the eighties, Quality, Safety and License Management were characterised by a static process of maintaining the licenses issued at the start of the facility. In the beginning of the eighties the regulatory body in the Netherlands required a more formal approach of Quality Assurance to be applied by the nuclear facilities in order to assure changes in operation to be in compliance with the changing license conditions.

In recent years a more and more dynamic Quality, Safety and Licensing Management has become necessary to comply with both stringent licensing requirements as well as a more market driven management of the nuclear facilities. In view of today's licensing policy of the competent authorities and in view of anticipated new fields of activities for all nuclear facilities a renewal and extension of NRG's site license is foreseen.

The Hot Cell Laboratories, built in the early 1960's, was originally designed for research on radioactive materials. In the past 30 years extensive research programmes have been carried out for of nuclear fuel and structural materials intended for light water reactors, fast breeder reactors and fusion reactor technology. In 1995 the laboratory has been expanded with a facility for the production of Mo99. This isotope is used to produce Tc99m, which is the most used isotope in the world for medical diagnostics. To investigate transmutation of long lasting fission products the Hot Cell Laboratories was extended with an actinide laboratory in 1997.

The continuing innovations of nuclear applications in the field of energy issues and nuclear medical science, and the growing public interest in nuclear environmental issues have strengthened the forces on safety and environmental aspects.

An integrated management system was implemented and certified for NRG in conformance with ISO 9001 and based on the ISO 14001 standards to meet the new goals.

The management system of the Hot Cell Laboratories has been laid down in a Technical Information Package (TIP), procedures, and supporting documents. The system itself is part of the NRG Management System.

## **2 NRG management system**

### **2.1 General**

NRG's Management System originates from ECN's Management System, which was certified in 1997. After NRG became an independent company the implemented management system was transformed to the new organisation.

Lloyd's Register Quality Assurance Ltd certified the system, which is based on the ISO 9001:1994 standard. The structure of our Management System reflects the structure of the organisation. This has led to a system consisting of management procedures, which are valid for all Product Groups within NRG, and supporting documents like work instructions, group and staff *specific documents as well as job descriptions and various forms.*

Quality, Safety and Environmental Dept (QSE) controls the general documents and periodically issues updated indices.

The Management System consists of 32 procedures covering Management & Organisation, Realisation, and Safety & Environmental aspects. Each procedure has been written in the form of a flow diagram, showing the responsible employees, their tasks and competence, the necessary and relevant input documents to be used in the process and the quantifiable output of the process.

*Specific work processes have been written down in Product Group specific documents. Within each Product Group a number of documents can exist and the group itself controls the documents.*

The NRG organisation is schematically given in figure 1, whereas the structure of the Management System is given in figures 2 and 3. The structure will be explained hereafter.

### **2.2 Structure**

In **Figure 2** the four main elements of the system are given namely:

#### **1. Mission**

This is the policy statement and reads: "The mission of NRG is to provide expertise and services in support of the safe, ecologically sound and efficient use of nuclear installations and develops and applies spin-off technology for the non-nuclear markets".

#### **2. Description of the structure**

As indicated before the NRG Management System originated from ECN's Management System, which was certified in 1997. An overview of the complete system is given in the NRG Index, consisting of general quality documents, general supporting documents and Product Groups documents. Schematically this is given in figure 3.

### 3. Management procedures

This element includes the Quality Manual and the Management Procedures. The Quality Manual describes amongst others the mission, organisation structure, and main responsible employees. The management procedures are not given in a descriptive way, but in the form of a flow chart. In the next chapter an example will be given and explained.

### 4. Supporting documents

This includes all supporting documents like various forms, checklists and relevant Product Groups documents. The documents are controlled by updated Indices.

### **3 The Hot Cell Laboratories**

#### **3.1 Documentation**

For the nuclear research activities specially built facilities are being used, where fission products and radioactive material can be processed. Consequently, the organisation has been licensed to handle these materials according to the Dutch Nuclear Energy Act. The license is based on a Design and Safety Report, in which a short description of the facilities and installations as well as a safety evaluation is presented. Next, a detailed description has been included with requirements and objectives that have to be met to operate the facility. This detailed information is given in the so-called Technical Information Package (TIP). The TIP is a living document, which describes the actual status of the facility, the way the objectives and requirements are achieved, and all updated revisions of the facility.

In short the TIP contains a description of the following subjects:

1. installations of research laboratory and their lay out;
2. identification and traceability (records) of fission products;
3. operational limits and conditions;
4. radioactive waste within the research laboratory;
5. safety analyses;
6. radiation protection.

#### **3.2 Quality implementation**

Based on the implemented management system a self-assessment was performed of the internal work processes and compared to the agreements written down in the management procedures. In this way the deficiencies between practice and theory were revealed and have to be corrected and put into compliance with the management procedures. The management procedures are valid for the whole company and describe main processes. They consist of 3 parts covering *Management & Organisation*, *Realisation*, and *Safety & Environmental Procedures*. Examples of parts are "Organisation and Job Description", "Management Review", "Customer Complaints", "Internal Audits", "Project Management", "Design Control", "Calibration of Instruments", "Maintenance of Equipment and Installations", and "Management of Environmental Effects and Labour Conditions". Specific knowledge and competence of personnel forms the basis for these procedures.

The lay out of the procedure is a flow chart, in which specific documents are mentioned, together with the various tasks of responsible employees. In this way input, actions, and output are quantifiable. Once all main activities of each process are listed it is easy to set up the flow chart, whereas it is also very conveniently. Activities are characterised by keywords and in this way each procedure is limited to one page only. However, the implementation of the procedures takes a lot of time explaining and defining these keywords.

The management procedures "Project Management" and "Maintenance of Equipment and Installations" are given in figures 4 and 5 respectively.

The primary laboratory work processes of each Product Group were identified and translated into specific procedures or instructions in the same way as for the management procedures, thus leading to specific Product Group related documents. These documents comply with specific requirements and therefore identify the group, and have a degree of flexibility.

An important supporting document within the Hot Cell Laboratories is for example a work instruction describing the identification and traceability of irradiated testing material. This document describes in detail the routing of samples during their presence in the laboratory. At any moment one can identify the exact location of a sample as well as its history.

#### **4 Audits**

To evaluate the effectiveness of the management system internal audits are performed twice a year. These audits are planned and controlled by the QSE Dept and performed by qualified internal auditors. Every non-compliance is registered, whereby the corrective measures to be taken and the responsible manager is indicated. The objective is to implement the corrective actions within the shortest time possible. QSE Dept monitors that all unsettled items will be solved.

A surveillance audit is performed each year by Lloyd's and is based on an audit program. Audit reports are registered in a general database and controlled by QSE. Management uses this database for obtaining trends and for monitoring the progress of measures to be taken as a result of the audits.

Next to this, the (national) license authorities perform audits, as a consequence of the Dutch Nuclear Energy Act, to evaluate the requirements according to the nuclear legislation. The objective of these audits is to check whether the license requirements are fulfilled.

## **5 Future**

After nearly 3 years of operation the management system is accepted and the awareness is increasing. This is expressed in decreasing the number of non-compliance reports, which has been submitted and resolved as well as the number of resolved audit reports. Nearly all the reports from 1997 and 1998 are resolved. In table 1 these figures are presented.

As a consequence of the merger NRG recognises two management systems, originating from both ECN and KEMA. The present activities will finally lead to one management system for both sites.

Recent developments from the energy and chemical industry require that safety and environmental risks be controlled in an adequate and identifiable way. A Safety Checklist for Contractors is used to evaluate these risks leading to a safety certification.

Next, the environmental management system will be integrated and finally the whole system shall meet the requirements according to the ISO 14000 standard.

table 1 Review of Resolved Reports after Implementation of Management System

Report Type	ECN Nuclear Research		ECN Nuclear Facilities		NRG R&D + Facilities	
	1997	1998	1997	1998	1998	1999*
<b>Improvement</b>	34	18	22	13	1	27
Resolved	34	17	21	13	0	12
Resolved in %	100	94	96	100	0	44
<b>Audit</b>	73	22	54	28	14	31
Resolved	73	22	53	27	12	18
Resolved in %	100	100	98	97	86	58

\* The 1999 figures from NRG are not yet settled; actions are ongoing  
As of October 1, 1999

# Figures

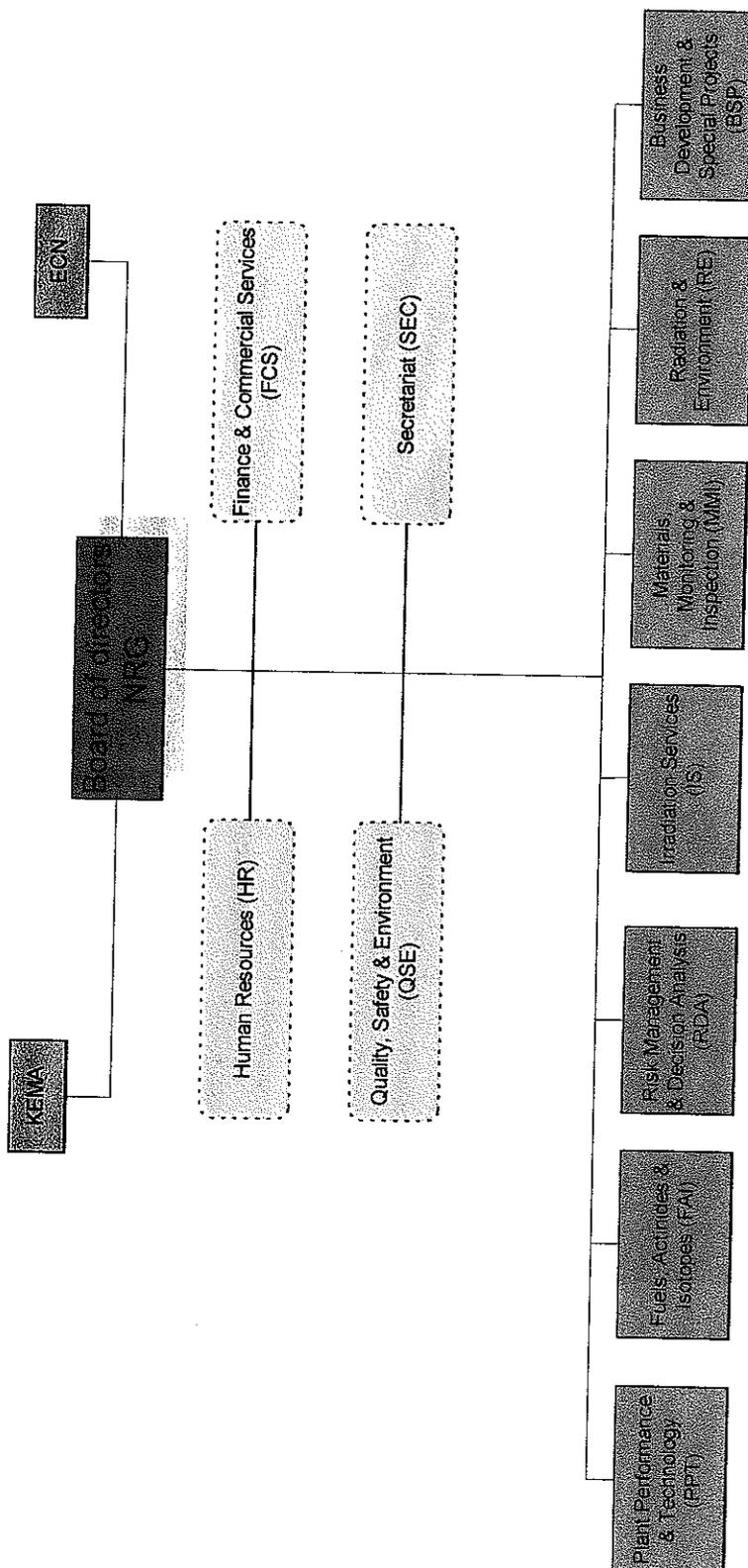


figure 1 NRG Organisation

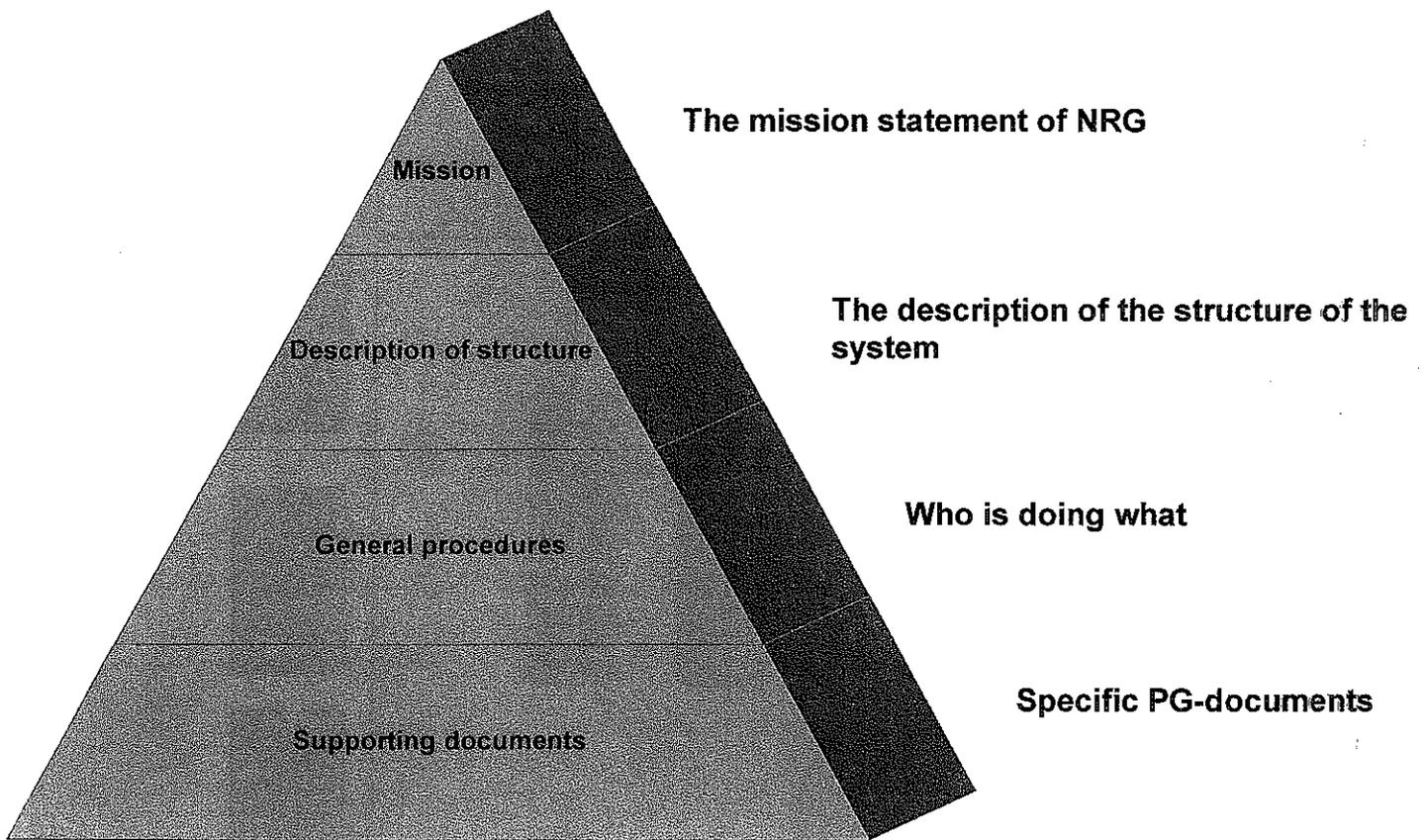


figure 2 Structure of Management System

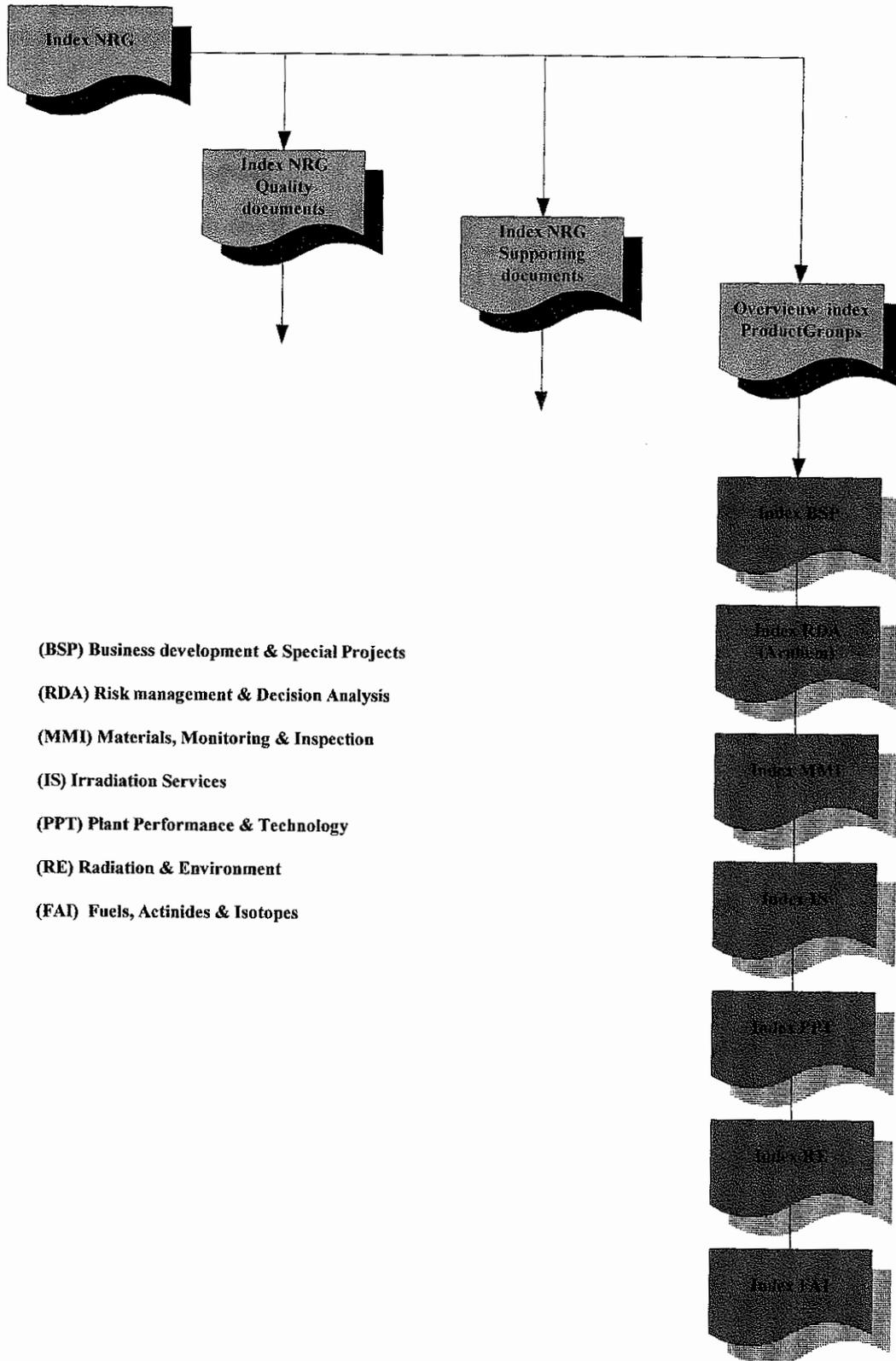
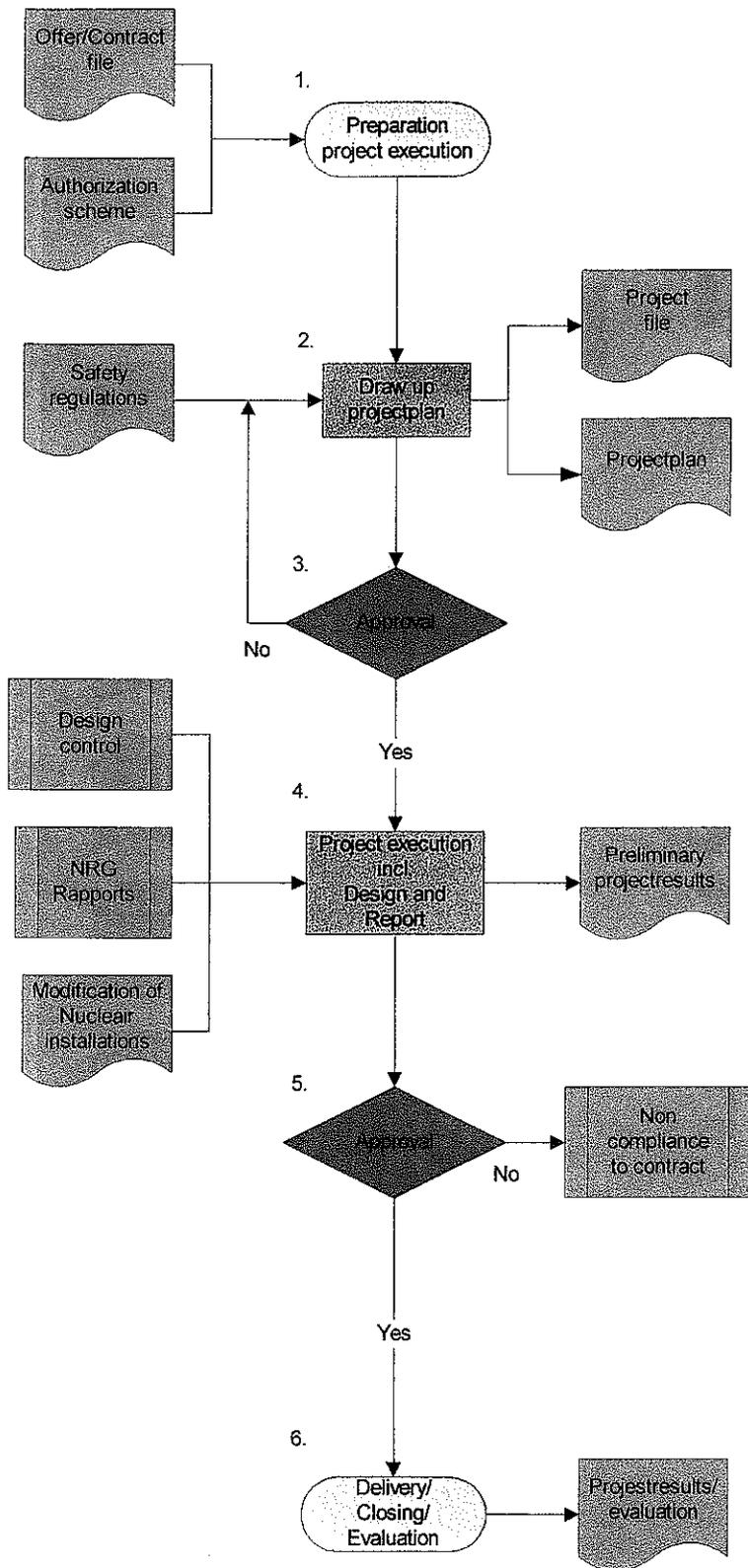


figure 3 Document Structure of Management System



**1. Managing Director/Product Manager**

- appoints Projectleader
- opens if necessary a budget

**2. Projectleader**

- initiates a projectfile
- draws up a projectplan in agreement with internal requirements

**3. Managing Director/Product Manager**

- evaluates projectplan and approves
- releases projectbudget

**Finance & Commercial Services**

- opens financial file
- records financial projectdata in administrative business system

**4. Projectleader**

- manages project, keeps up projectfile
- maintains contacts with customer
- reports to Managing Director/Product-manager about progress and non compliances
- delivers preliminary results

**5. Managing Director/Product Manager**

- checks project results
- starts if necessary Non Compliance Procedure

**6. Managing Director/Product Manager**

- decides if project evaluation is needed
- starts if customer is not satisfied the Non Compliance Procedure

**Projectleader**

- takes care of delivery of project results to customer
- draws up the projectevaluation
- prepares project data for filing

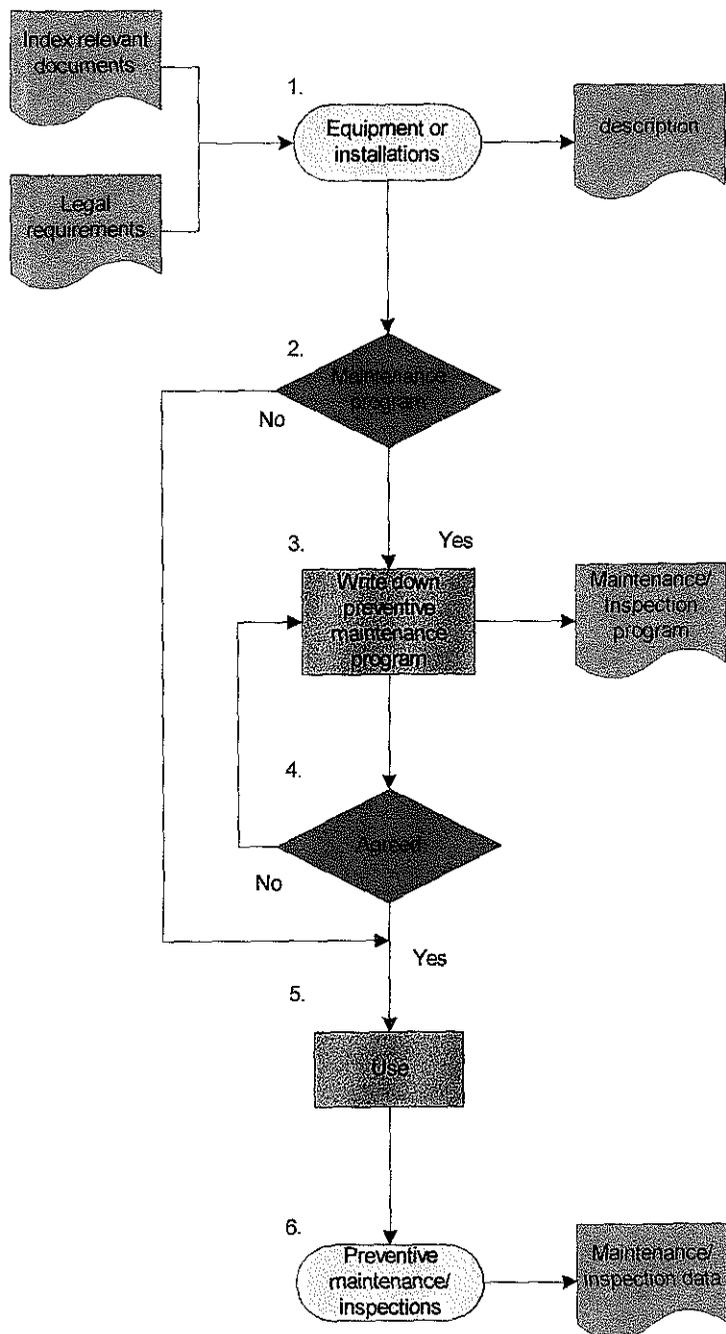
**Managing Director/Product Manager**

- assesses project evaluation
- decides on closing down the project

**Finance & Commercial Services**

- closes down the project financially and administratively

figure 4 Management Procedure "Project Management"



**1. Productgroup manager**

- appoints responsible engineer
- Responsible engineer**
- defines if description is necessary
- takes care for description

**2. Productgroup manager**

- evaluates if preventive maintenance is necessary

**3. Responsible engineer**

- writes down a maintenance program and adjust if necessary

**4. Productgroup manager**

- evaluates maintenance program and/or adjustments and approves it

**5. User**

- reports defects to responsible engineer
- Responsible engineer**
- prevents further use
- takes care for corrective maintenance
- releases

**6. Responsible engineer**

- takes care for implementation, lays down information information and makes a record

figure 5 Management Procedure "Maintenance of Equipment and Installations"

