Royaume du Maroc

CNESTEN

Centre National de l'Energie, des Sciences et des Techniques Nucléaires

Kingdom of Morocco

National Center for Nuclear Energy Science and Technology

Experience on implementing CNESTEN's Management System

AZIZ LAMZADRHI
Head of the Quality Management System department/ CNESTEN - *B.P 1382 RP10001-Rabat -Morocco*

lamzadrhi@cnesten.org.ma

Technical Meeting on Integrated Management Systems for the Sustainable Safe Operation and Effective Utilization of Research Reactors.
16 to 19 JUNE 2025 - Mito, Japan .

Outline

1. CNESTEN s Presentation & organization .
2. Process MAP of CNESTEN
3. Reactor Process Mappin
4. Legal framework and main references
5. TRIGA MARK II Research Reactor : utilization and Organization
6. IMS Implementation Objectives
7. IMS implementation steps
8. Scope and application field
9. IMS Commitment
10. Documentary structure of our MS
11. System assessement
12. Lesson learned / Problems we encoutered
13. Conclusion

CNESTEN’s Presentation

the National Center for Nuclear Energy Science and Technology is a public institution created in 1986 and placed under the Minister of Energy Transition and sustainable development.

Being a public establishment with a scientific, technical and commercial vocation; and exercising its activities in accordance with the national legislative and regulatory framework in matters of nuclear and radiological safety and security, the CNESTEN is responsible for :

1- Promote scientific research and applications of nuclear techniques in different socio-economic sectors of the country,including health, industry ,environment, hydrology…

CNESTEN's Presentation

2- play a role as technical support organization to the national authorities in safety and security /

3- prepare the technological basis for the introduction of nuclear power.

4-Radioactive waste management.

Since 2003, CNESTEN operates several facilities and implements various nuclear techniques for a wide range of activities at the Nuclear Studies Centre located at the Maâmora Forest (30Kms North of Rabat)

CNESTEN works on behalf of institutions / ministerial departments and private clients.

CNESTEN's Presentation

Radioactive Wast Management

Research Reactor
(TRIGA Mark II, 2 MW)

Life science
Radioisotope Production

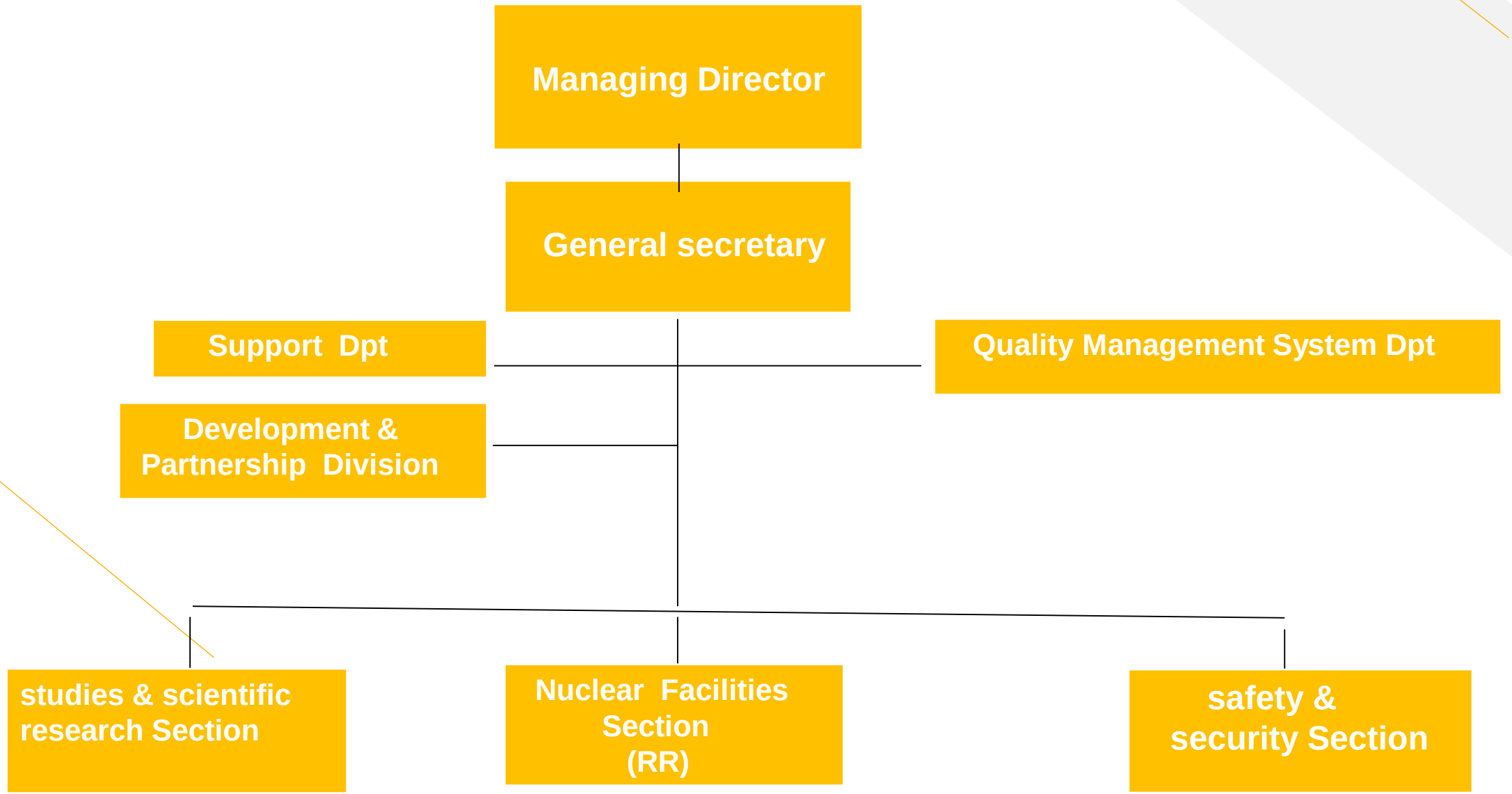
CENM Training Center

Industrial Applications
Non-Destructive Testing

Safety & Security

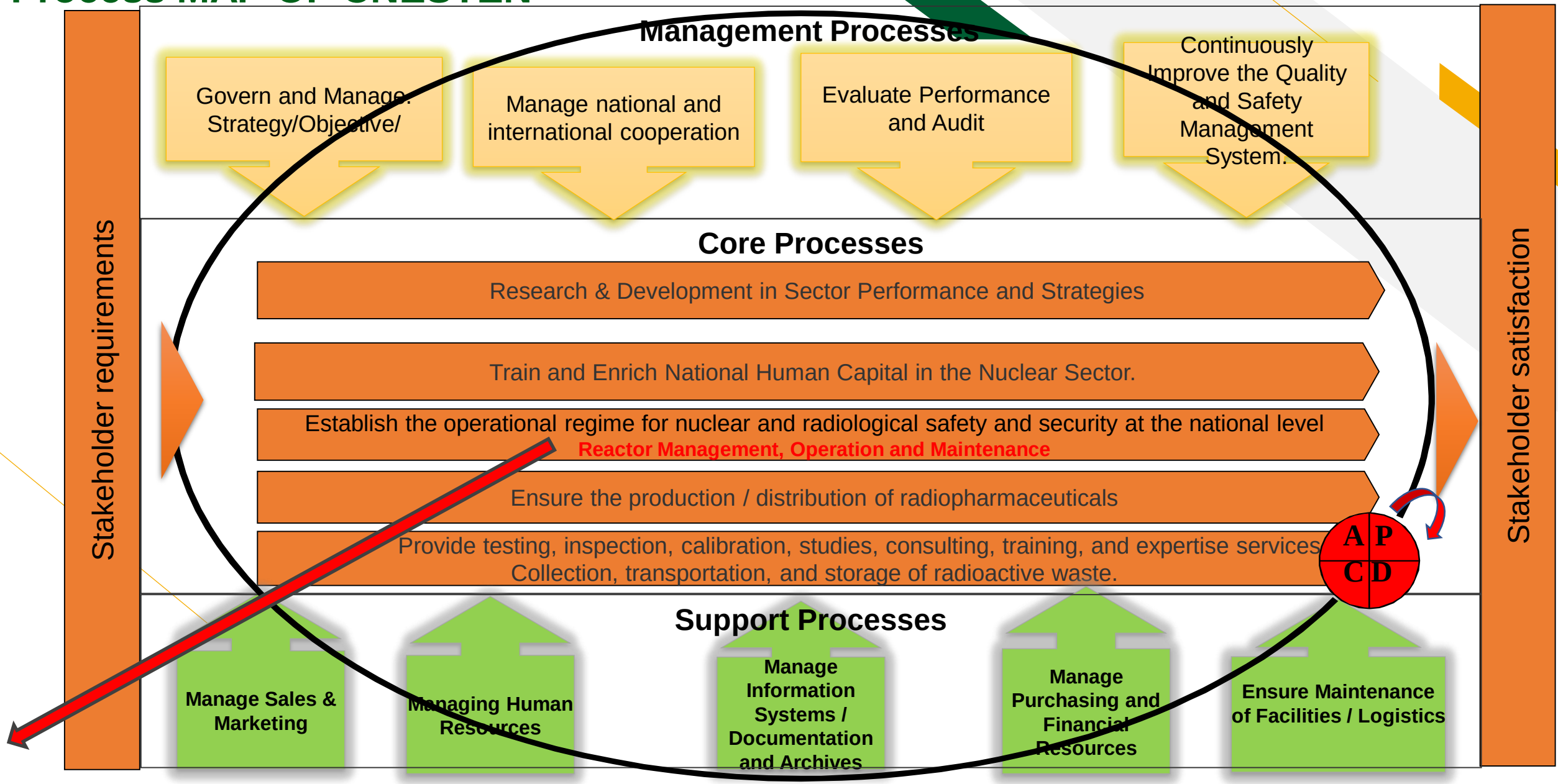
Earth Sciences
Research &
Development

CNESTEN´s presentation: Organization

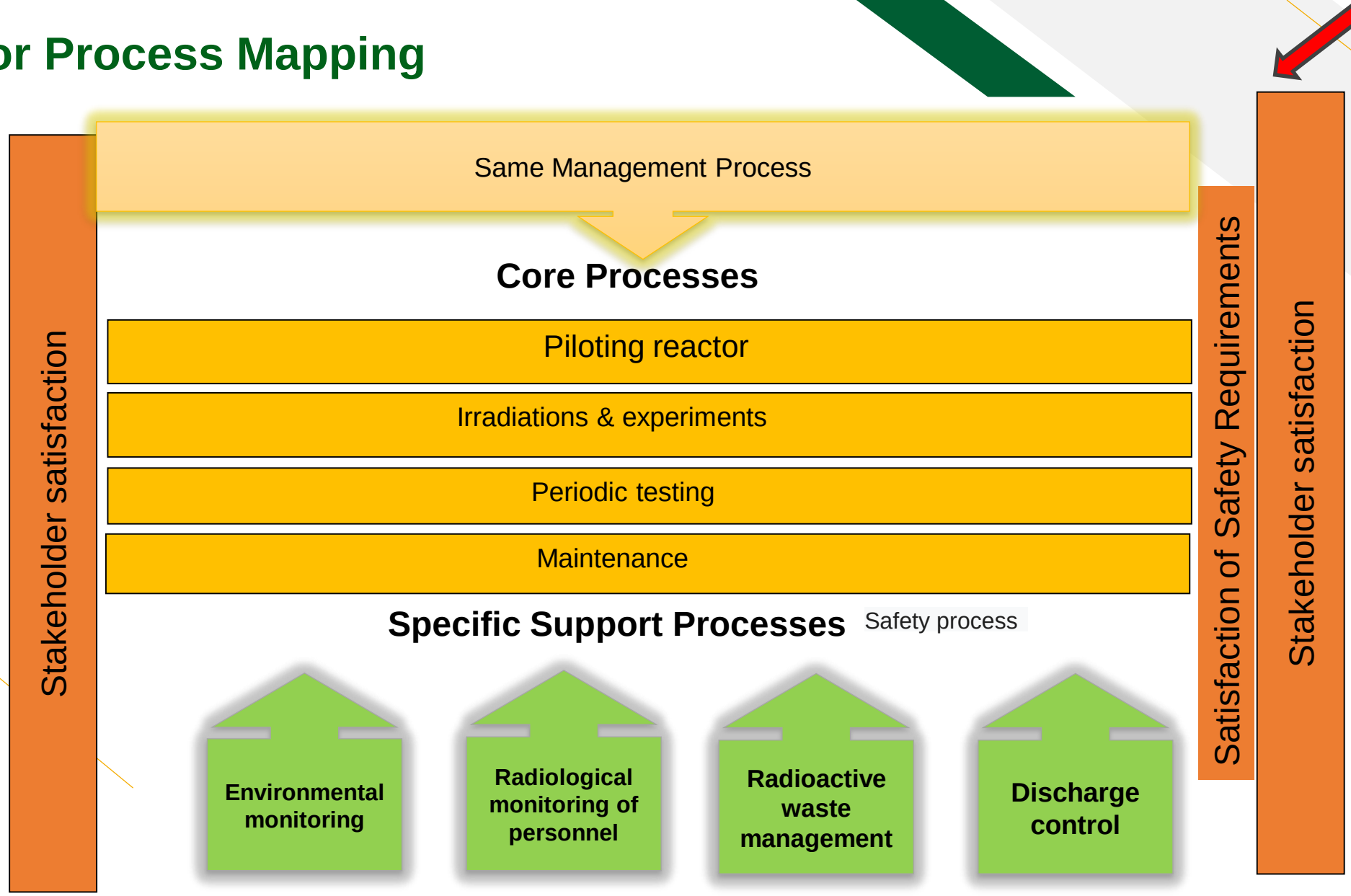


219 Agents including: 36 % of Engineers and PhD. 63% Managerial position and Technicians

Process MAP OF CNESTEN



Reactor Process Mapping



Legal framework and main references

- The Quality Assurance 142-12 program is an essential legal and regulatory framework to guarantee nuclear and radiological safety and security in Morocco (Law No. 142-12 relating to nuclear and radiological safety and security and the creation of the Moroccan Agency for Nuclear and Radiological Safety and Security)

The Quality Assurance 142-12 program

IAEA Safety Standards

Management System

Safety report for the TRIGA Mark II reactor

CNESTEN Quality Manual

Internal Safety and Security Regulations
ISO standards

Documents on Safety Culture

Satisfaction of all requirements

Safety – Health –Security –Quality –Commercial - Others

TRIGA MARK II Research Reactor : utilization and Organization

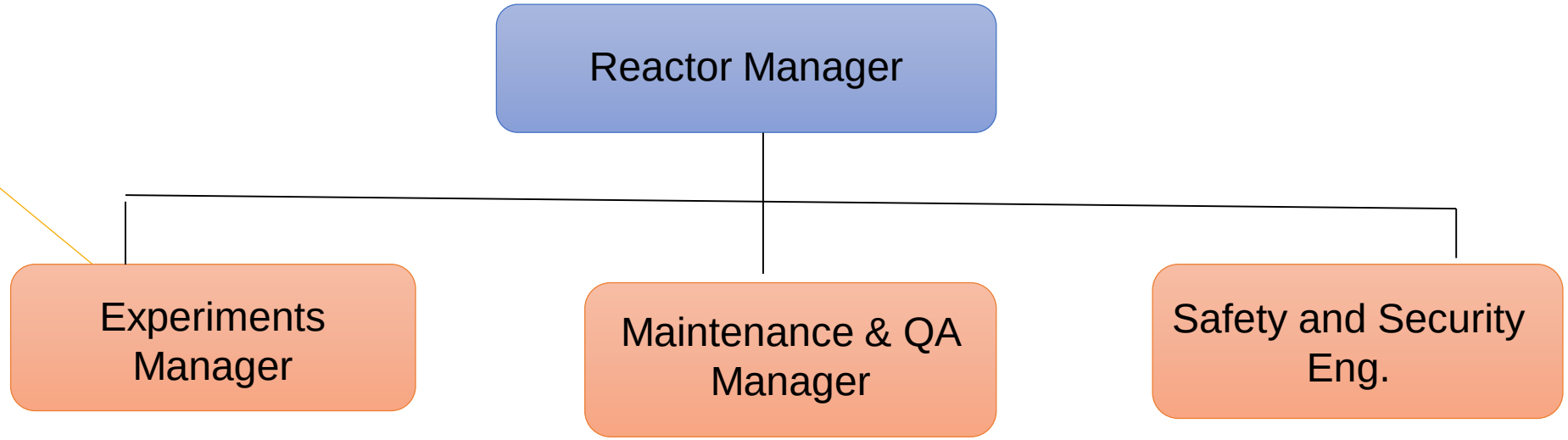
the reactor is operated to meet demands of experimental programs and service work

1. Neutron Activation Analysis

2. Iodine 131 production

3. Fiber optic Irradiation

4. Education and Training:



IMS Implementation Objectives

Since its creation, CNESTEN has organized its operations based on a quality management system based on a process approach and is committed to a continuous improvement process to ensure the consistent and efficient execution of its various activities

CNESTEN adopts a Quality Management System, combining, in addition (with priority) to national legislative and regulatory requirements for nuclear and radiological safety and security, the following reference standards :

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Centre National de l'Energie, des Sciences et des Techniques Nucléaires
National Centre for Nuclear Energy, Science and Technology

CNESTEN

المملكة المغربية
المركز الوطني للطاقة والعلوم والتقنيات النووية

Cnesten Quality Policy Statement

Depuis sa création, le CNESTEN organise son fonctionnement en s'appuyant sur un système de management qualité fondé sur une approche par processus, et s'engage dans une démarche d'amélioration continue, afin d'assurer la réalisation de ses différentes activités d'une manière cohérente et efficiente.
Ayant atteint aujourd'hui une position reconnue dans ses métiers d'expertise, de formation, de contrôle, d'essais et d'étalonnage, le CNESTEN adopte un Système de Management Qualité (SMQ), associant, en plus des exigences législatives et règlementaires nationales de sûreté et de sécurité nucléaires et radiologiques, les normes de références suivantes :

- Le Guide des Bonnes Pratiques de Fabrication BPF pour la fabrication des médicaments radio pharmaceutiques ;
- La norme NM ISO 9001 pour sa démarche de Management par la qualité ;
- La norme NM ISO /CEI 17025 pour ses laboratoires, d'essais et d'étalonnage ;
- La norme NM ISO/CEI 17020 pour le fonctionnement des entités procédant au contrôle ;
- La norme NM ISO/CEI 17024 pour les entités de certification procédant à la certification de personnes.

La mutation de l'environnement et le rôle croissant des parties prenantes font que la qualité constitue un axe stratégique de développement dont les objectifs sont :

- La mobilisation de l'ensemble du personnel autour de notre démarche, acte d'engagement collectif et d'épanouissement individuel ;
- L'amélioration de la qualité de nos prestations et le renforcement de notre image de marque ;
- La satisfaction des besoins et des exigences de nos clients et leur fidélisation ;
- Le maintien et le renforcement de l'excellence scientifique ;
- L'amélioration permanente du SMQ de nos prestations et de la maîtrise de nos processus ;
- L'acquisition de la reconnaissance nationale et internationale des compétences en matière d'expertise, de formation, de contrôle, d'essais et d'étalonnage.

La pérennité des activités du CNESTEN, ses performances et la confiance de ses clients sont des priorités qui justifient notre démarche en matière de qualité. Cela requiert une mobilisation et un engagement constant de l'ensemble du personnel.

Pour maintenir l'efficacité de notre SMQ, et tout en préservant l'impartialité de nos prestations, je m'engage personnellement à apporter mon plein soutient ainsi que les ressources nécessaires pour y parvenir, C'est dans cette intention que je désigne Mr. Aziz LAMZADRHI, en tant que Responsable du Système de Management Qualité, lui confiant, entre autres, les responsabilités suivantes de :

- S'assurer que la politique qualité est comprise, mise en œuvre dans toutes les entités fonctionnelles et opérationnelles et à tous les niveaux ;
- Représenter la Direction Générale du CNESTEN dans les domaines relatifs à la qualité ;
- Animer, développer et contrôler les actions et les objectifs des différentes entités du CNESTEN pour la mise en œuvre de la politique qualité ;
- Vérifier la réalisation des objectifs qualité ;
- Rendre compte à la Direction Générale du fonctionnement du SMQ et proposer toute action pour l'amélioration de notre politique qualité.

A cet effet, j'appelle l'ensemble du personnel à :

- Respecter les exigences des normes de références adoptées, les exigences législatives et réglementaires en vigueur ainsi que celles des organisations fournissant la reconnaissance ;
- Considérer la satisfaction des clients comme priorité majeure ;
- S'engager dans la démarche qualité afin d'assurer sa réussite et son amélioration continue par l'application de toute la documentation établie dans le cadre du système mis en place

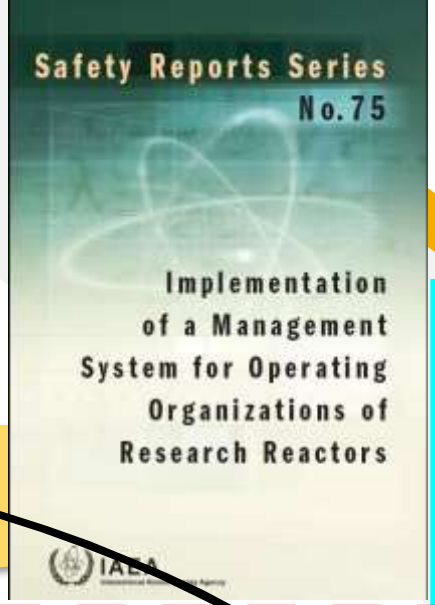
LE DIRECTEUR GENERAL DU CNESTEN
Mr HAMID MARAH

Original Signed

IMS Implementation Objectives

«compliance standard»	«standards for demonstrating competence, impartiality and consistency of activity in CNESTEN »	
In compliance with national law 142.12 and IAEA standards	GMP	Good Manufacturing Practices for radiopharmaceutical drugs
ISO 9001 QMS	NM ISO CEI / 17025 :2018	For the competence of calibration and testing laboratories, including sampling
	NM ISO/CEI 17020: 2012	for the operation of entities carrying out controls and inspections
Quality Audit – Guidelines		
ISO 19 011	NM ISO / CEI 17024 : 2013	for entities carrying out certification of individuals at the center

IMS implementation steps



Scope of application, context and criteria

Needs Of IP/Field OF MS and its processes

EFFECTIVE COMMUNICATION

Leadership
Commitment to safety / policy

Roles, responsibilities and authorities

Team / project manager

From all the involved organizational units/ training

Planing

Quality objectives
Actions related to risks and opportunities
Resources human and financial

Process

Product and Service Requirements
regulatory requirements; and
IAEA standards

Assessement

Safety Culture self-assessment
Independent Assessment
Audit
Management review
Periodic Safety Review

Improvement

Gap analysis

plan | **DO** | **CHECK** | **ACT**

A P C D

Identification of stakeholders

promotion of strong safety culture

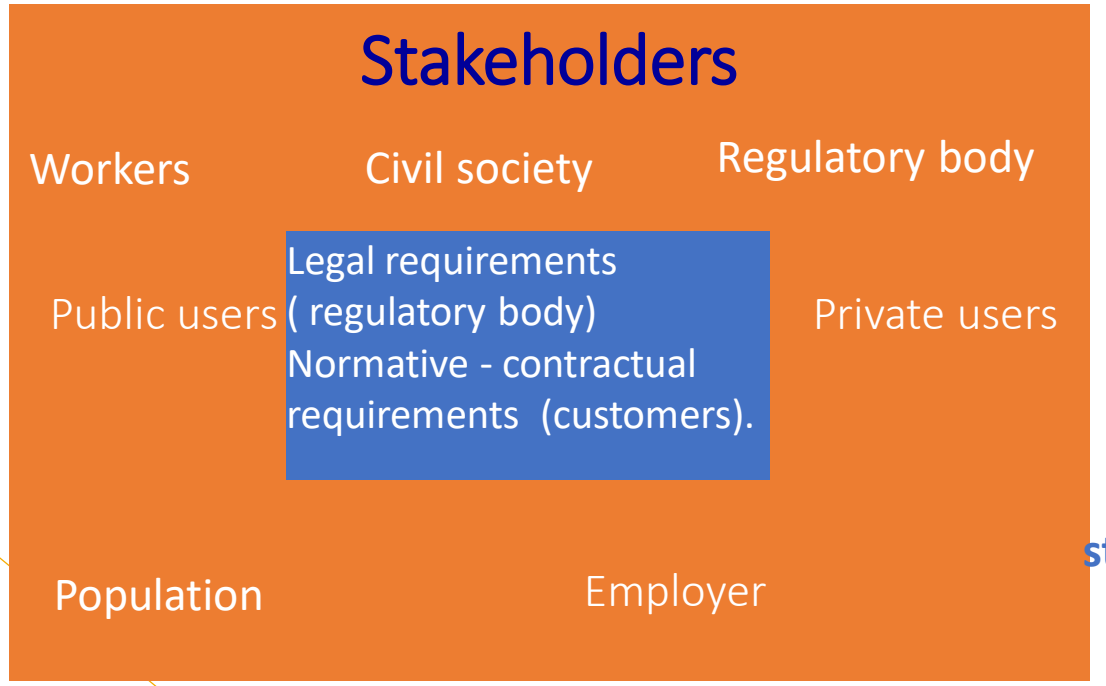
GRADED APPROACH TO ENSURE A FIT-FOR-PURPOSE SYSTEM

Management System / Integration Challenge

Follow up and control

IMS implementation steps

identification of stakeholders



Satisfaction of stakeholders' requirements

- Effectiveness
- Safety
- Security
- Efficiency

Scope and application field

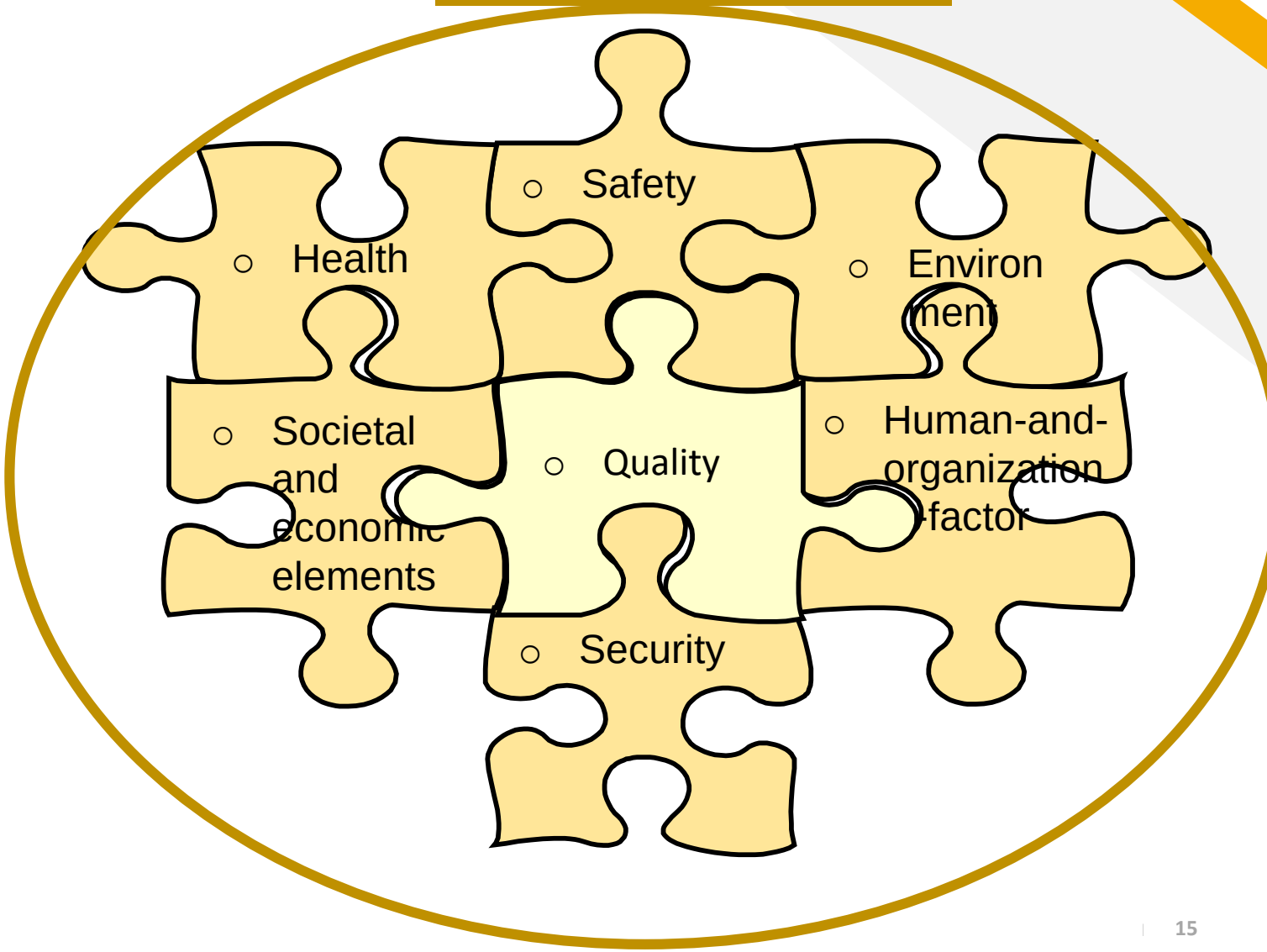
Management systems are designed to integrate :

IAEA Safety Standards
for protecting people and the environment

Leadership and
Management for Safety

General Safety Requirements
No. GSR Part 2

IAEA
International Atomic Energy Agency



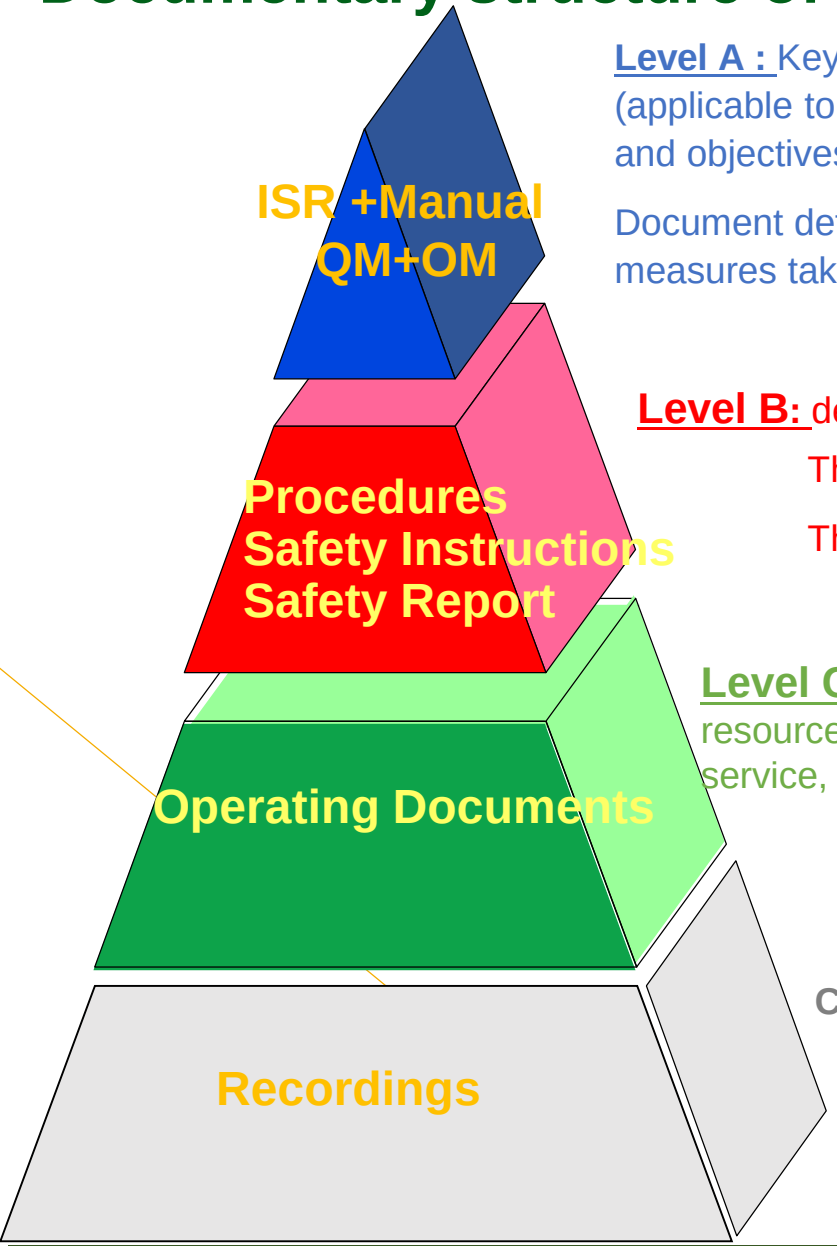
IMS Commitment

CNESTEN has a Quality Committee and a Quality Management System department reporting directly to General Management.

The IMS aims to continuously improve performance. Aware of this challenge, CNESTEN is already committed to this approach through:

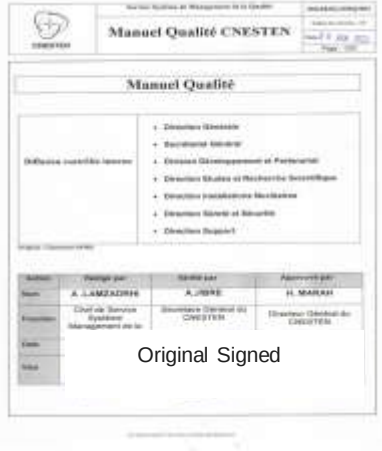
- ✓ Implementation of the ISO 9001 standard and integration with safety and security requirements
- ✓ Harmonization of internal safety regulation documents with the quality management system
- ✓ Development of the integrated quality and safety policy
- ✓ Training of quality network coordinators representing all sectors of activity at CNESTEN
- ✓ Harmonization of quality and safety terminology within the center for a unified system

Documentary structure of our MS



Level A : Key documents describing the management system at the cross-functional level (applicable to all CNESTEN entities). In accordance with the established global quality policy and objectives.

Document defining the policy and organization of CNESTEN and describing the general measures taken to ensure the safety, security and quality of its products or services.



Level B: describes the processes and activities required to implement the management system

They explain how the different actions take place

They answer the questions: who, what, where, how?

Level C: Includes detailed working documents/ defining the operational procedures, resources and sequence of quality-related activities relating to a particular product, service, contract or project.

Constitute proof that the quality system is working well.

QM: Qualily Manual : policy statement + organizational chart + process mapping

OM :Organization Manual : job descriptions + Nominative organization chart

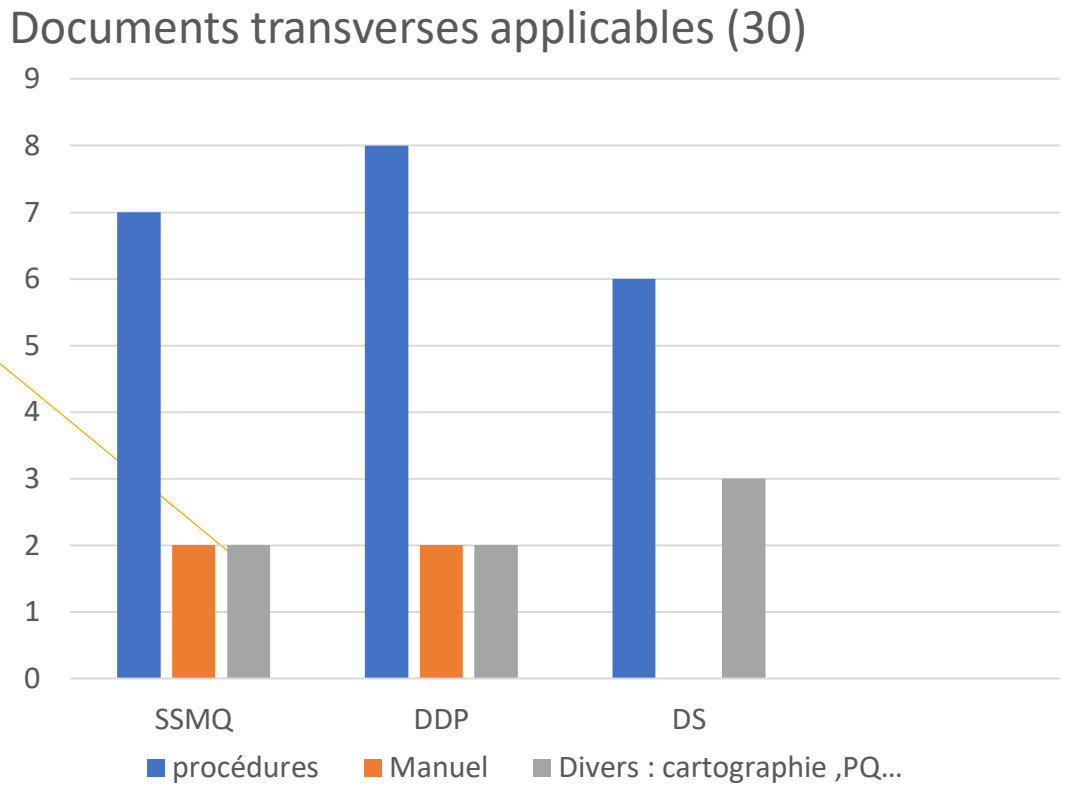
ISR : Internal Safety Regulations safety and security requirements

structure adopted at the transverse level; and at the level of each entity or area of activity

Documentary structure of our MS

multi-referential MS managed by:

- ✓ Policy statement (including the regulatory aspect of safety and security)
- ✓ Procedure for managing the document system and the procedure for controlling records in terms of :



- ✓ Creation.
- ✓ Presentation,
- ✓ Revision and Modification,
- ✓ Codification,
- ✓ Writing,
- ✓ verification,
- ✓ approval,
- ✓ Distribution,
- ✓ Duplication and filing Archiving,
- ✓ cancellation and destruction

Documentary structure of our MS

Transversal documents

non-exhaustive list

General

Applicable at CNESTEN Level

- List of quality documents* applicable to CNESTEN.
- Document Control Procedure
- Record Control Procedure
- **CNESTEN Quality Manual**
- Management Review Procedure
- **Internal Audit Procedure**
- **CNESTEN Organization Manual**
- Internal Quality Management Audit Procedure
- **Risk and Opportunity Procedure**
- **Nonconformity Management and Corrective Action Procedure**
- Audit Report (ISO/IEC 17025:2017) (no. 20xx/x/0xx)
- Auditor/Technical Expert Report (ISO/IEC 17025:2017)

- Commercial Procedure
- Complaints Handling Procedure
- Customer Satisfaction Measurement Procedure
- Internship Management and Organization Procedure
- Visits Management and Organization Procedure
- Scientific and Technical Events Management and Organization Procedure
- SC Document Management Procedure
- CFSTN Specific Organization Manual
- CFSTN Quality Manual
- CFSTN Document Management Procedure
- Recovery Procedure

- Recruitment Procedure
- Continuing Training Procedure
- Scientific Equipment Maintenance Procedure
- CNESTEN Purchasing Procedure
- External Supplier Selection and Evaluation Procedure
- Annual Staff Evaluation Procedure

Internal Safety and Security Regulations

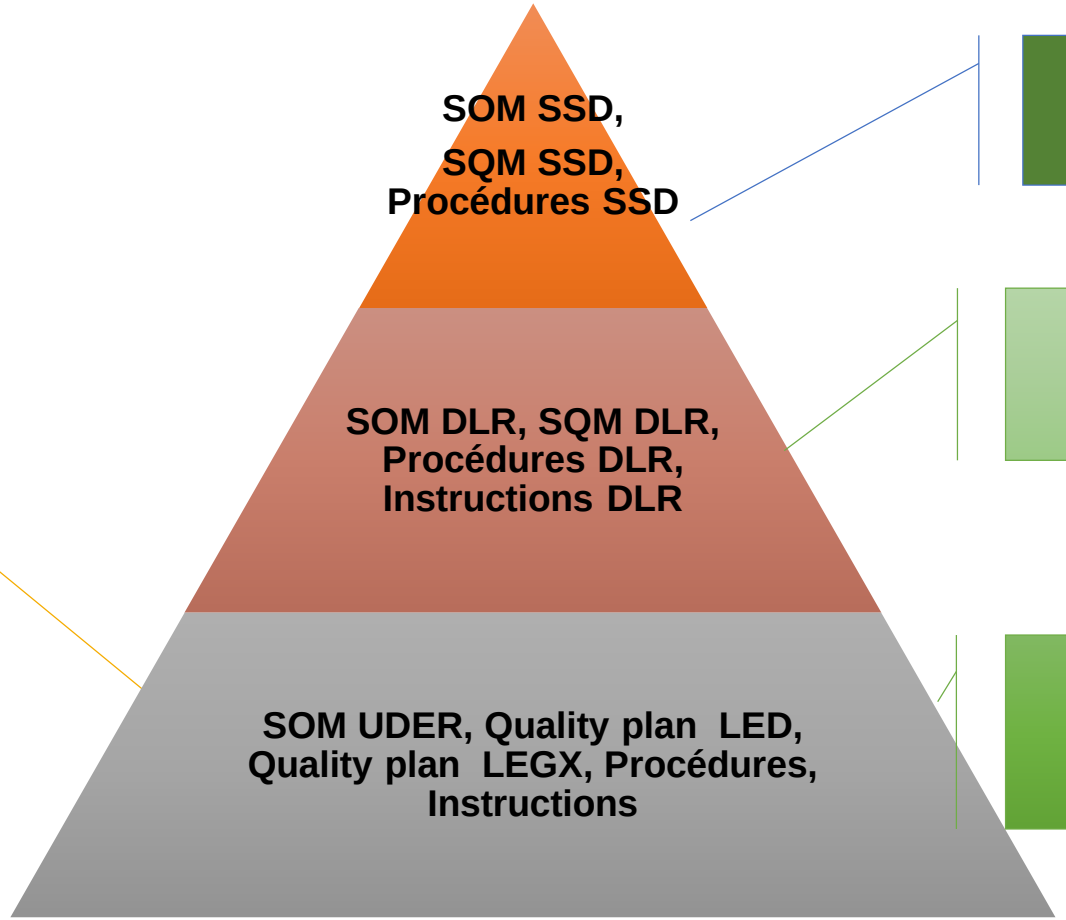
- Security Organization at CNESTEN
- Missions of the Safety and Security Unit
- CNESTEN Security Committee
- Management of Liquid Effluents
- Organization of On-Call Duty
- Security Committee
- Missions of the Facility Manager

- Classification and Protection of Documents and Information
- Organization and Implementation of the Internal Plan
- Authorized Personnel in Charge of Reactor Operation
- Transport of Radioactive Materials
- Access Management
- Appointment of Facility Managers and Security Coordinators

*strictly for internal use and are therefore confidential.

Documentary structure of our MS

Example of the Safety and Security Departement



55 documents applicables

40 documents applicables

100 documents applicables

SQM: Quality Manual Specific to the field and requirements of this entity
policy statement + organizational chart + process mapping

SOM :Specific Organization Manual of this entity
job descriptions + Nominative organization chart

DLR : Dosimetry, SSDL and Monitoring Network Unit

Documentary structure of our MS

Operating

- Pre-startup check
- Startup procedure
- Reactor operating modes
- Startup instructions: shutdown of the reactor pool water purification system
- Startup instructions: shutdown of the primary cooling circuit
- Startup instructions: shutdown of the secondary cooling circuit
- Startup instructions: shutdown of the spent fuel storage pool purification circuit
- Filling the demineralized water storage tanks
- Demineralized water top-up
- Verifying proper operation of nuclear ventilation
- Switching from normal ventilation to emergency ventilation
- Fuel handling procedure
- Radioactive material handling and manipulation procedure
- Daily round checklist
- Action in case of alarms

Experimentation

- Procedure for Using the Experimental Devices of the TRIGA MARK II Reactor at the CENM in Maâmora
- Safety Requirements for Conducting Experiments in the TRIGA Reactor at the CENM
- Loading/Unloading Samples into the Rotating Rack
- Pneumatic Transfer System
- Procedure for Removing an Irradiated Target from the Central Sock or Lazy Susan
- Procedure for Retrieving an Irradiated Target in the Radiochemistry Laboratory
- Authorization to Conduct Experiments in the TRIGA MII Reactor at the CENM
- Procedure for Inserting and Removing a Target from the Central Sock

Interface

- Management of interfaces and reciprocal responsibilities between the various units of the Reactor Module
- Interface protocol between the reactor control unit and the radiopharmaceutical production unit
- Interface protocol between the reactor control unit and the waste exploitation unit
- Interface protocol between the reactor control unit and the Safety and Security Department
- Interface protocol between the reactor control unit and the Instrumentation and Industrial Applications Department
- Interface protocol between the reactor control unit and the Technical and Logistics Department
- Interface protocol between the reactor control unit and the Nuclear Electronics and Instrumentation Unit
- Interface protocol between the reactor control unit and the Materials Sciences Unit
- Interface protocol between the reactor control unit and the electronic instrumentation team

specific

Management system RR

non-exhaustive list

Accreditation process

NM ISO/IEC 17025:2018 accredited laboratories - since 2003

- Dosimetry and calibration laboratories, in order to comply with the authority's approvals (law no. 142-12)
  - ❑calibration for handheld radiation protection devices
  - ❑Monitoring of the external exposure of staff
- laboratory for structural and isotopic analysis
  - ❑Measurement of stable isotopes in liquid samples
  - ❑Measurement of radioactivity in liquid samples

N° AL 128.01/2021

N° AL 128.02/2021

N° AL 128.03/2021

Extension to accréditation NM ISO / IEC 17020* : 2012

- ❑Inspection and control entities in radiation protection at CNESTEN

*in progress (file submitted to the accreditation body)

System assessement

- ✓ Inspection by regulatory authorities
- ✓ Internal audits (according to annual audit programs) and management review
- ✓ Safety Culture related assessment
- ✓ External audits of accreditation bodies

CNESTEN	Service Système de Management de la Qualité	Misc/SAQ/005 - Al
	Programme Annuel d'Audits Internes. Année : 20>4	Indice de révision : 02
		Date : 06/12/2023
		Page : 1/1

Réf: SSMQ / 01/ 24

Main / Entité	Janv	Fév	Mars	Avr	Mai	Juin	Juil	Août	Sept	Oct	Nov	Déc
DSS/DLR/UDER Réf: NM ISO / CEI 17025 : 2018			06.07 et 08 M&T									
DERS / DEL Réf: NM ISO / CEI 17025 : 2018						04.05 et 06 M&T						
DSS/DPTS/URP Réf: NM ISO / CEI 17020 : 2012					13.14 et 15 M&T							
DPR Réf: BPF des médicaments											au cours de la 4 ème semaine M&T	
DSS/DPTS/URP Réf: NM ISO / CEI 17024 : 2013									au cours de la 4 ème semaine M&T			

M : Management T : Technique

Date / visa du RE / RSMQ :

Original Signed

Date / Validation de la Direction Générale :

Original Signed

Lesson learned / Problems we encoutered

Harmonization of safety and security requirements with regulatory and normative requirements (ISO/CEI 17025 – ISO/CEI 17020…) requires a certain level of competence and knowledge management to ensure **efficiency**.

Ensure the commitment of functional entities because many support processes are not fully executed by reactor staff.

knowing how to set a priority plan according to the context and the issues (SWOT) because it is a systematic and graduated approach

Adopting the integrated approach to managing RR operations reduces organizational risks.

The difficulty of implementing the IMS depends on the systems already in place.(Easier when nothing is in place)

The level of expertise, workload, ability to work in a team as well as process management

Conclusion

This integrated management approach constitutes a strategic decision for the organization / RR that can help it improve its overall performance and provide a solid basis for initiatives aimed at ensuring its sustainability.

Certain resources such as an integrated management software package are essential for an IMS especially in situations of small staff and high turnover.

A complacent integrated management system does not achieve the benefits of a system that is embedded in the organization's culture.

Implementing an IMS is an important future challenge for all organizations / RR, but it remains an initial project; it is only the beginning of an improvement process that must continue.

Royaume du Maroc

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lamzadrhi@cnesten.org.ma

Thank you for your kind attention.

www.cnesten.org.ma/