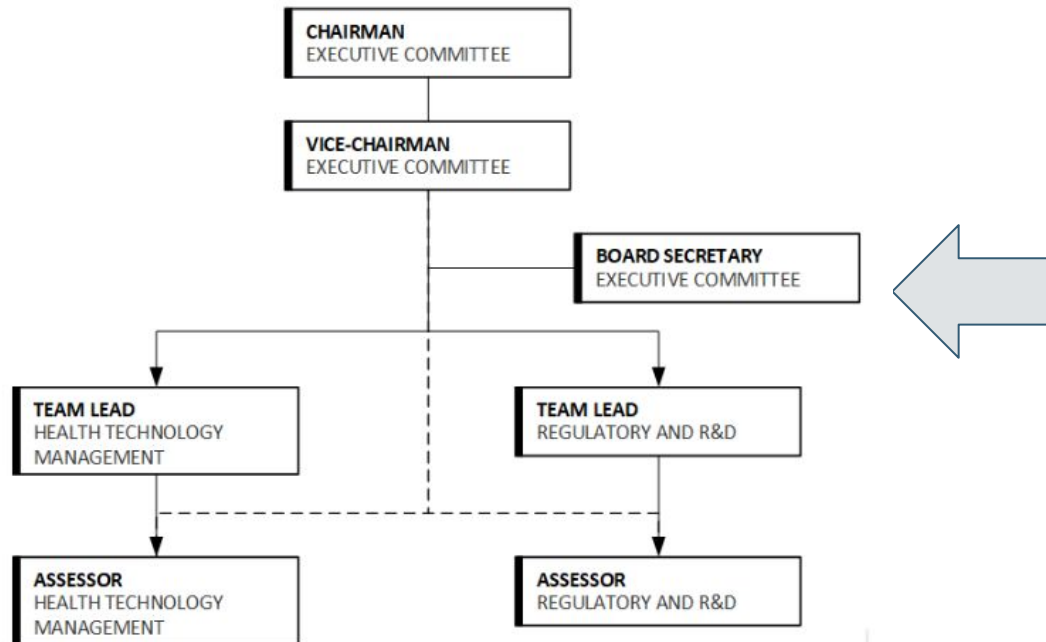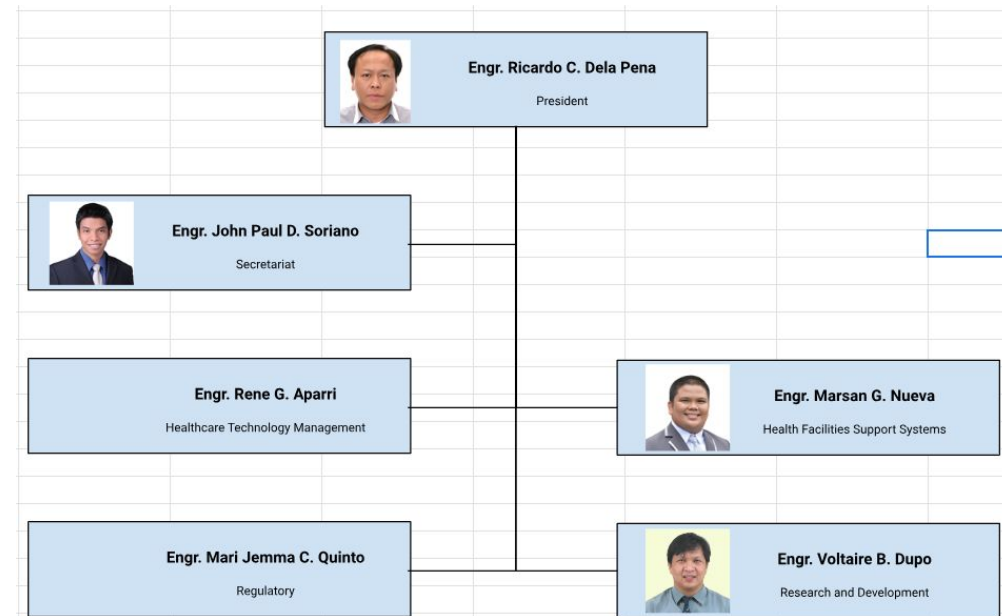Discussion for Re-aligned Materials
Prepared by Voltaire Dupo

IECEP BES

REORGANIZED SOCIETY
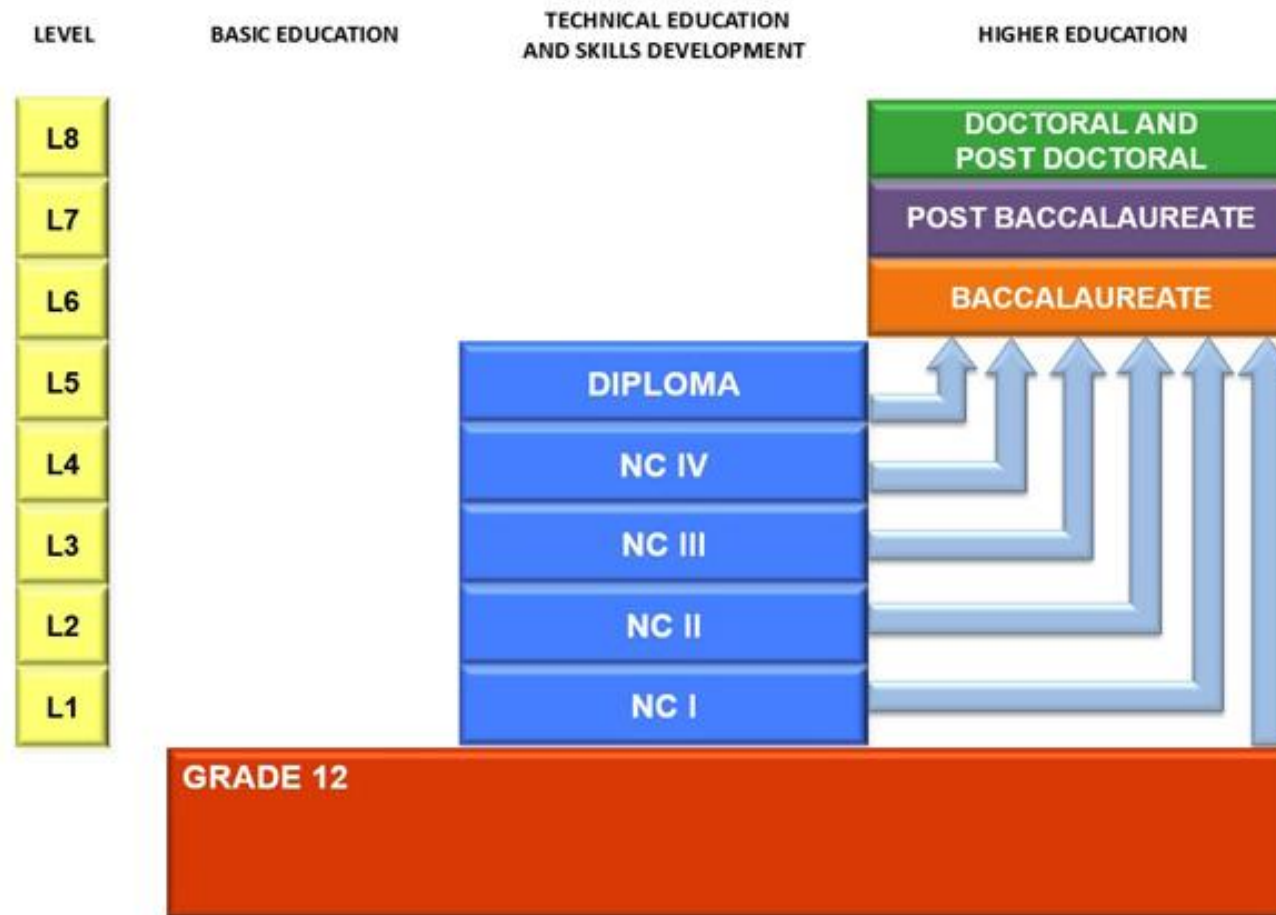
ORIGINAL ORGANIZATION OF SOCIETY

OUR RESPONSIBILITY CURRENTLY AFTER REORGANIZATION

- Determine the Goals of PQF Level 8

- Determine the Learning Requirement for PQF Level 8

- Develop an Assessment System for PQF Level 8

- Provide the framework to differentiate PQF Levels 6,7 and 8 from each other

- Provide pathway for enforce RA 9292 Provision on National Implementing Agencies

  - Why is a Medical Engineer in the DOH Policy Non - Existent? They have ME, Civil Engineers in the books for Facilities but no ECEs?

  - Why is TESDA NC II qualification requirement enforced by DOH while ECE PRC Licenceis ignored?

FUNCTIONS AND RESPONSIBILITIES OF PQ

as per PQF-NCC Resolution No. 2014-03 adopted on December 11, 2014

The PHL Qualifications Framework

LEVEL	BASIC EDUCATION	TECHNICAL EDUCATION AND SKILLS DEVELOPMENT	HIGHER EDUCATION
L8			DOCTORAL AND POST DOCTORAL
L7			POST BACCALAUREATE
L6			BACCALAUREATE
L5		DIPLOMA	
L4		NC IV	
L3		NC III	
L2		NC II	
L1		NC I	
	GRADE 12		

FUNCTIONS AND RESPONSIBILITIES OF PQF LEVELS

The PHL Qualifications Framework

as per PQF-NCC Resolution No. 2014-03 adopted on December 11, 2014

LEVEL	BASIC EDUCATION	TECHNICAL EDUCATION AND SKILLS DEVELOPMENT	HIGHER EDUCATION
L8			DOCTORAL AND POST DOCTORAL
L7			POST BACCALAUREATE
L6			BACCALAUREATE
L5		DIPLOMA	
L4		NC IV	
L3		NC III	
L2		NC II	
L1		NC I	
	GRADE 12		

? — Academe — Doctoral Degree

Professional Engineer — M Sc Degree Graduate
Licensed Engineer — B Sc Degree Graduate
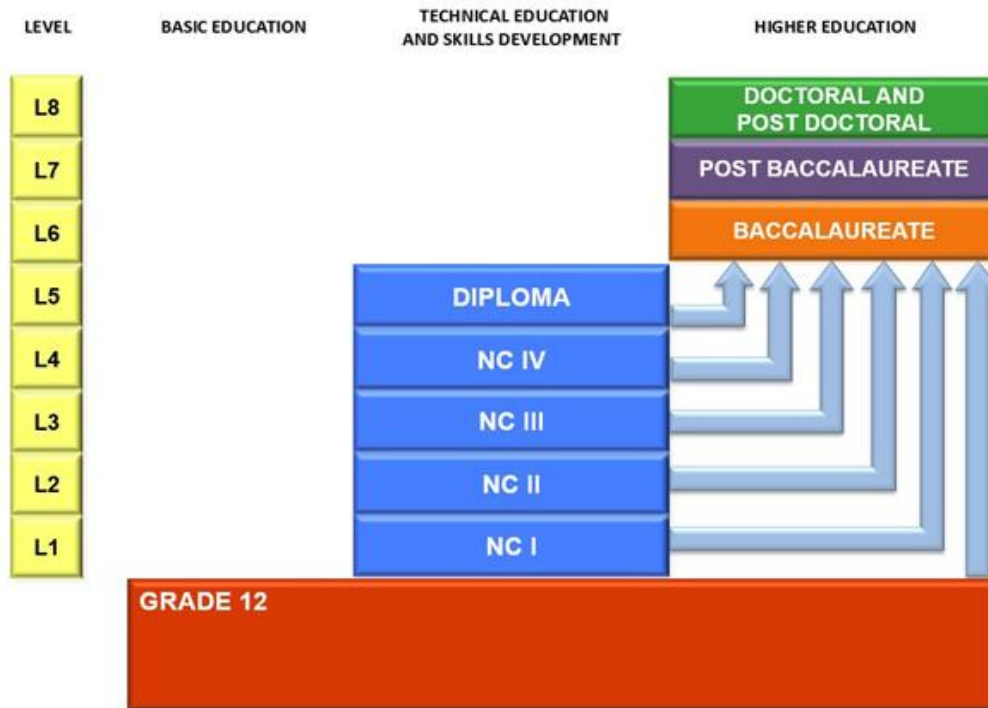
Shop Supervisor — Technical Skills Holder

Advanced Technician

Technician

Operator

ISO 17024

States in creating a Certification there is a need to define the following

- Job to be done
  - Skills / Abilities need to do the job
  - Knowledge needed to do the job
  - Metrics to define the level of skill / ability to perform the job
  - Metrics needed to measure the retention of knowledge held on a required information make decisions that concern the job
- A measurement tool do define how the applicant is current holding the knowledge or skills to be qualified for the job that he/she has applied for.
- A process to follow in light of the results of measuring how he/she is ready for it.

ISO 17024

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- A measurement tool do define how the applicant is current holding the knowledge or skills to be qualified for the job that he/she has applied for.
- A process to follow in light of the results of measuring how he/she is ready for it.

Specifications
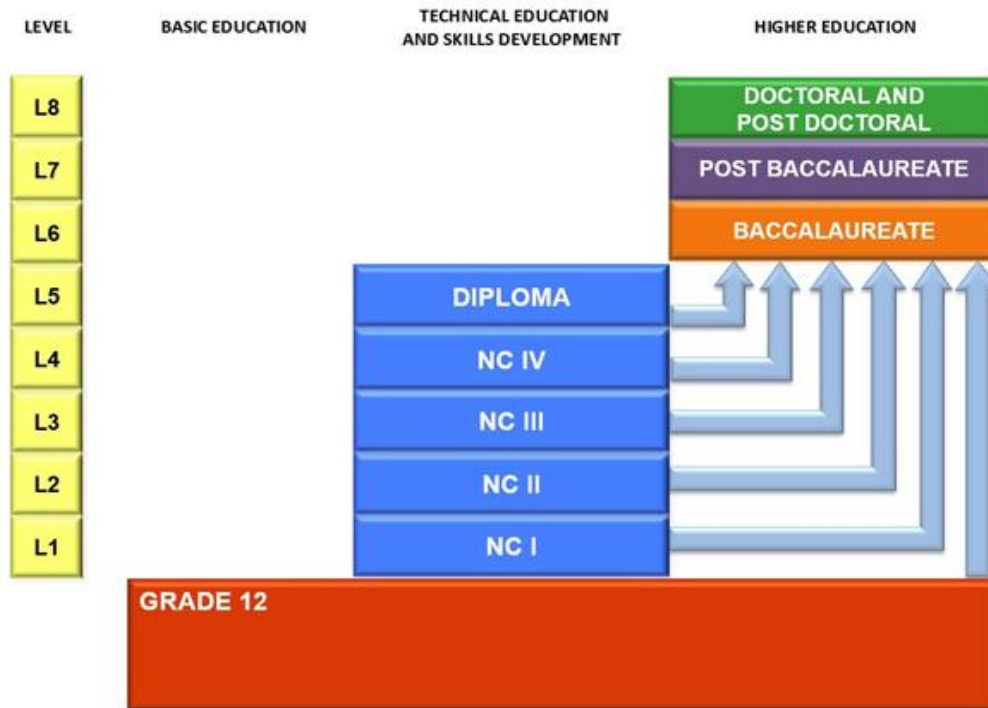
Training Requirements

Pre-Assessment

Training Requirements

FUNCTIONS AND RESPONSIBILITIES OF PQF LEVELS

as per PQF-NCC Resolution No. 2014-03 adopted on December 11, 2014

The PHL Qualifications Framework

LEVEL	BASIC EDUCATION	TECHNICAL EDUCATION AND SKILLS DEVELOPMENT	HIGHER EDUCATION		Academe
L8			DOCTORAL AND POST DOCTORAL	?	Doctoral Degree (PhD/DEng)
L7			POST BACCALAUREATE	Professional Engineer	M Sc / MEP Degree Graduate
L6			BACCALAUREATE	Licensed Engineer	B Sc Degree Graduate
L5		DIPLOMA		Shop Supervisor	Technical Skills Holder
L4		NC IV		Advanced Technician	
L3		NC III		Technician	
L2		NC II		Operator	
L1		NC I			
	GRADE 12				

FUNCTIONS AND RESPONSIBILITIES OF PQF LVL 6

as per PQF-NCC Resolution No. 2014-03 adopted on December 11, 2014

The PHL Qualifications Framework

LEVEL	BASIC EDUCATION	TECHNICAL EDUCATION AND SKILLS DEVELOPMENT	HIGHER EDUCATION
L8			DOCTORAL AND POST DOCTORAL
L7			POST BACCALAUREATE
L6			BACCALAUREATE
L5		DIPLOMA	
L4		NC IV	
L3		NC III	
L2		NC II	
L1		NC I	
GRADE 12			

?
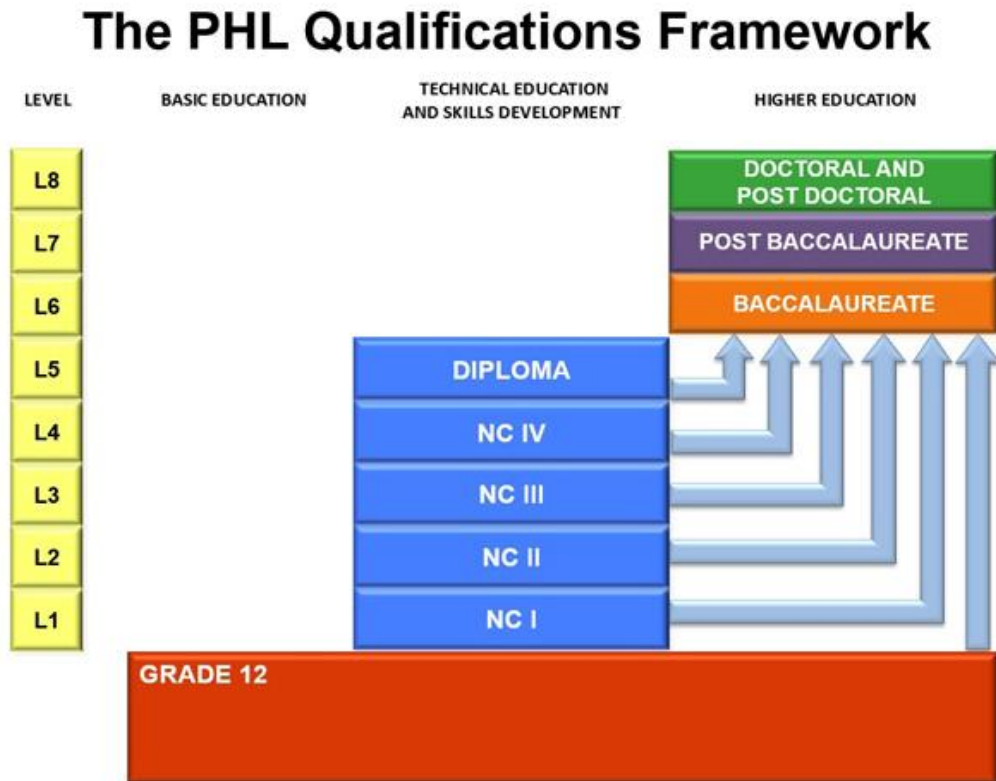
Professional Engineer
Licensed Engineer

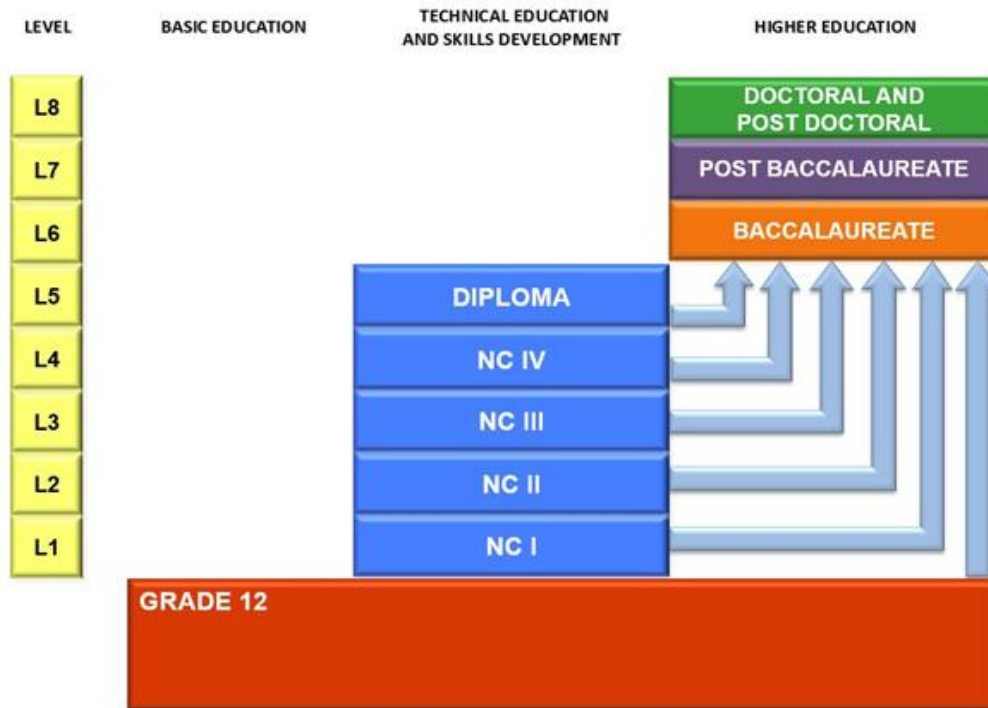Creates Electronic Systems
Oversees:
- Medical / Non Medical Electronic Devices
- Communications Equipment
- Supervision of Teams
- Designs Control Systems

Legal / Legislative Basis: RA 9292

FUNCTIONS AND RESPONSIBILITIES OF PQF LVL 7

as per PQF-NCC Resolution No. 2014-03 adopted on December 11, 2014

The PHL Qualifications Framework

| LEVEL	BASIC EDUCATION	TECHNICAL EDUCATION AND SKILLS DEVELOPMENT	HIGHER EDUCATION
L8			DOCTORAL AND POST DOCTORAL
L7			POST BACCALAUREATE
L6			BACCALAUREATE
L5		DIPLOMA	
L4		NC IV	
L3		NC III	
L2		NC II	
L1		NC I	
	GRADE 12		

?

Professional Engineer
Licensed Engineer

Designs Electronic / Communication Systems
Checks and Validates Designed Systems
Oversees Commissioning and Upkeep of Systems

Legal / Legislative Basis: RA 9292

PROPOSED FUNCTIONS AND RESPONSIBILITIES OF PQF LVL 8

as per PQF-NCC Resolution No. 2014-03 adopted on December 11, 2014

The PHL Qualifications Framework
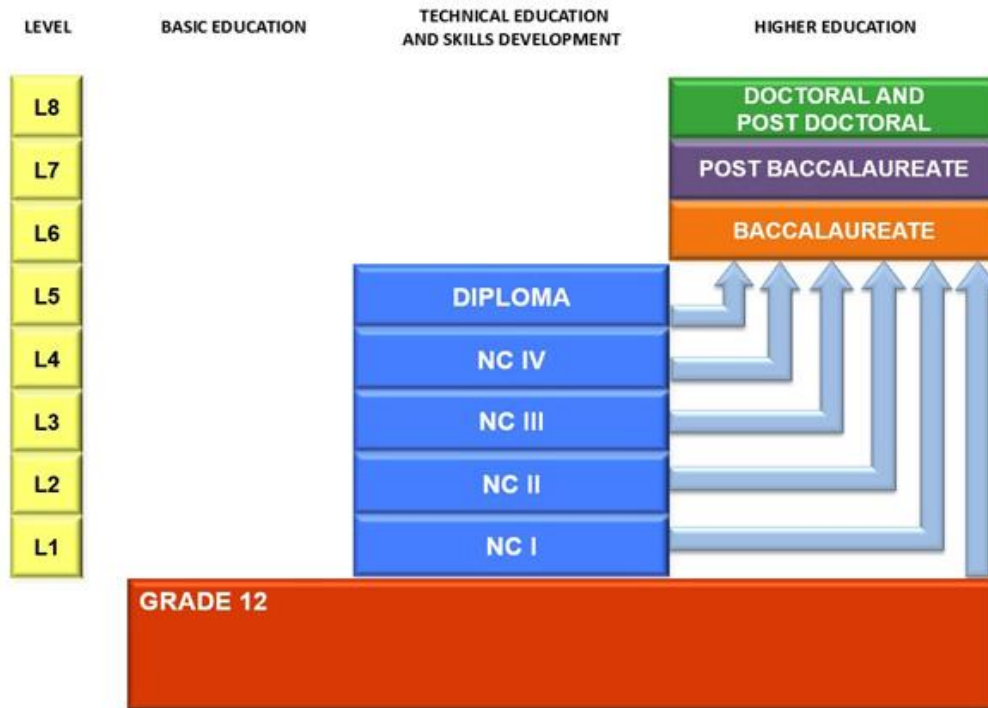
Administer Operations for a Company, Government Office

Consult on New Technology
- Introduced
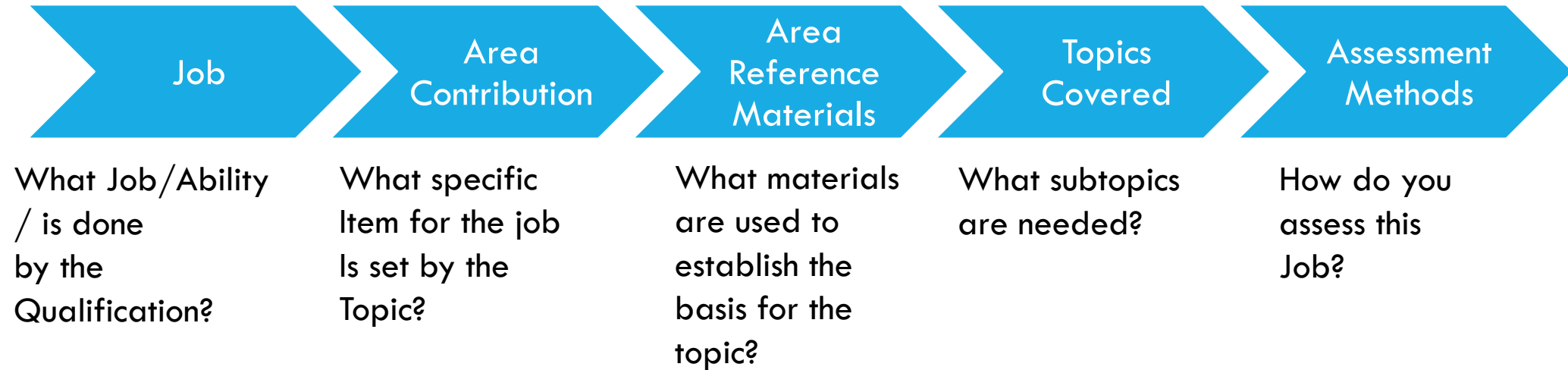- Developed In Country

Influence National Policy Guidelines

Develop New Systems covering commercialization

Develop New Technology / Concepts

ISO 17024 APPLIED TO OUR REQUIREMENT

❑ Assigned an informal Title to PQF Level 8 for the Industry Practicioners

❑ Finalize the definition of the Job of a PQF Level 8 engineer

❑ Select the required competence levels for each job

❑ Identify the Abilities / Skills Needed to do the Job

❑ Reference a clear set of information or instructions as a guide to doing or preparing to accomplish a job.

❑ Build the Assessment System based on the:
   ❑ Defined Job / Task
   ❑ Identify the Ability / Skill Needed to Perform the Job
   ❑ Use the reference to define the knowledge and framework to do the Job

FRAMEWORK

Job	Area Contribution	Area Reference Materials	Topics Covered	Assessment Methods
What Job/Ability / is done by the Qualification?	What specific Item for the job Is set by the Topic?	What materials are used to establish the basis for the topic?	What subtopics are needed?	How do you assess this Job?

ISO 17024

	1	Scope Description	What is the Name of this Qualification Segment
	2	Official Description	Based on Official Law or Regulatory Memorandum Order what is the Official Description of the Qualification?
	3	Jobs and Tasks	What are the official tasks and jobs does carrying this Qualification imply that the receiver can do?
	4	Required Competence	What is the required competence that is manifested by the individual? This can be based on a specific job, knowledge held or skills.
	5	Abilities	What is the abilities that is manifested by the individual? These are talents or aptitudes. It can also be physical capabilities relating to hearing and mobility.
	6	Pre-requisite	These are qualifications or competence that are needed before one can be certified. This is not often necessary to have but when it is present the pre-requiste should be related to the Required Competence.
	7	Code of conduct	Does the applicant abide by the code of conduct that is promoted and enforced by IECEP? Does he not have any criminal record meaning any court ruling related to his penalization for offenses related to his professional life. Note pending court cases not yet ruled on is not part of this since we work on a system of innocent until proven guilty.

Criteria for Initial Certification

On Site Assessment	Do we have an Assessment Sheet for Onsite Work Done and Documentation from Supervisors? Do we include client evaluations if the one wanting to receive the qualification is a free lance engineer and takes accounts from clients?
Professional Development	List of Attended Seminars or Training related to the qualification that he/she is applying for.
Checks on Physical Capability	Refers to Abilities listed in the general description if the one applying for the certification declares it as his/her physical ability / capacity.

Pre-requisite to obtaining requirements	Evidence related to showing that he can support Listed Competencies covered by the qualification with any past training certification that he/she received.

Assessment Methods for Initial Certification

- On Site Assessment Table
- Professional Development Record
- Interview Guidelines
- Exam Questionairre
- Assessment Tool for Physical Capability

Surveillance Methods

	Yearly Reports for the First 6 years of Certification
	Renewal Reports for the Corresponding years after two renewals from start of Licence Effectivity

Criteria for Suspension

	Gross Misconduct in Extension of Services to Clients

Consideration of fair representation of all parties (Academe, Industry)

TOPICS

OLD SET

Healthcare Technology Management	
Laboratory	
Critical and Operative	
Therapeutic	
Diagnostic Imaging	
Sterilizations	
Nephrology	
General Devices	
Electrical Safety	
Service and Asset Management	
Regulatory	
Industry Standards	
Technical Standards	IEC standards
Safety Standards	
Health Technology Assessment	
Planning and Design	
Health Facility Support System	
Nurse Call	
Pnuematic Tube Systems	
HIS/LIS/RIS/PACS	
Waste Management and Disposal Systems	
Negative & Positive Pressure / HEPA Filtration Systems	
Medical Gases	
Research and Development	Engr. Dupo
Emerging Technologies	
Research Ethics	
IoT	
Artificial Intelligence	
Risk Management	
Regulatory Requirements	

NEW Proposed Set

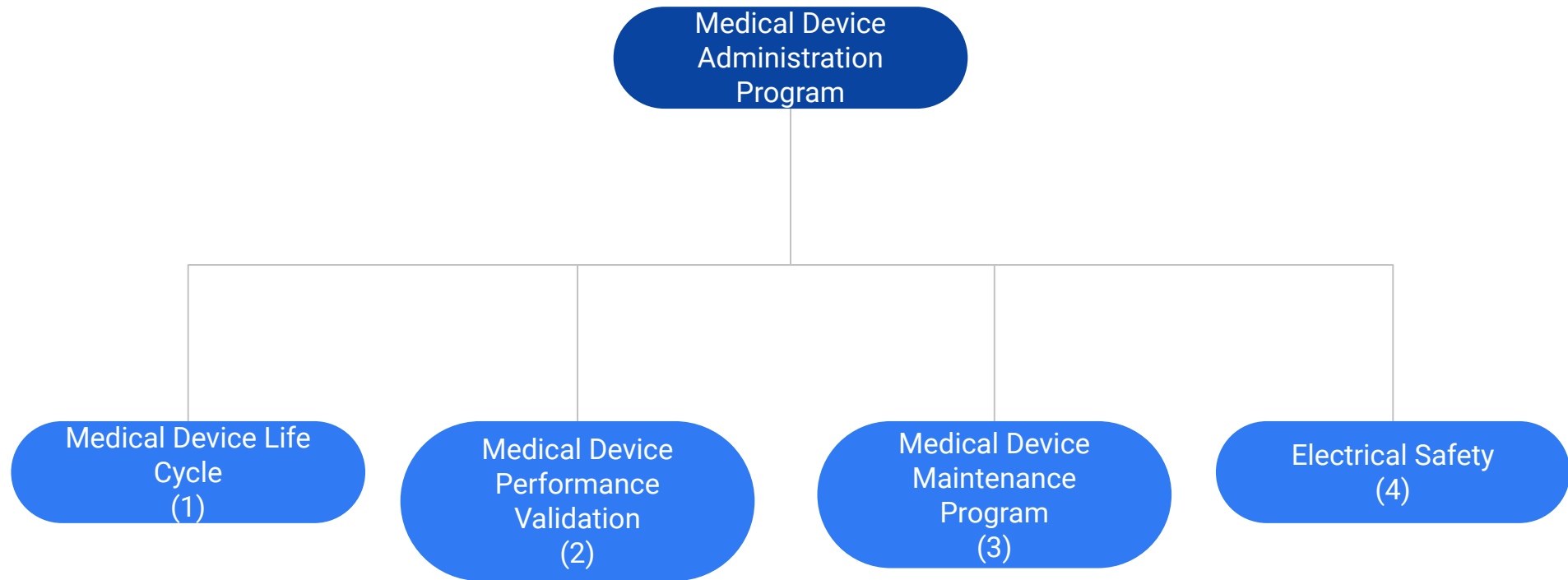| Competency Matrix	Topics
Common	• Medical Device Administration Program • Quality Administration System • Medical Device Regulation • Data Privacy
Advanced	• Risk Control
Elective	• Research Ethics • Electromagnetic Compliance

Program Names and Study Materials

Program Names	Course Hours	Standard Materials Used for Reference
Core 1: Medical Device Administration Program	40	AS/NZS 3551
Core 2: Quality Administration System	40	ISO 13485, Quality of Care Measurements, Planning and Design
Core 3: Medical Device Regulation	40	RA 9711 FDA Act, FDA Circular 2021-002, FDA Circular No. 2023-002, Asean Medical Directive
Core 4: Data Privacy	40	RA 10173, IRR for RA 10173
Advanced 1: Risk Control	8	ISO 14173 and Added Directive for Predicting Failure
Elective 1: Electromagnetic Compliance	30	CISPR 11, CISPR 14
Elective 2: Research Ethics	40	ISO 14155 Clinical investigation of medical devices for human subjects — Good clinical practice;Department of Agriculture Administrative Order No. 40 Series of 1999 RULES AND REGULATIONS ON THE CONDUCT OF SCIENTIFIC PROCEDURES USING ANIMALS,National Ethical Guidelines for Health and Health-Related Research 2017

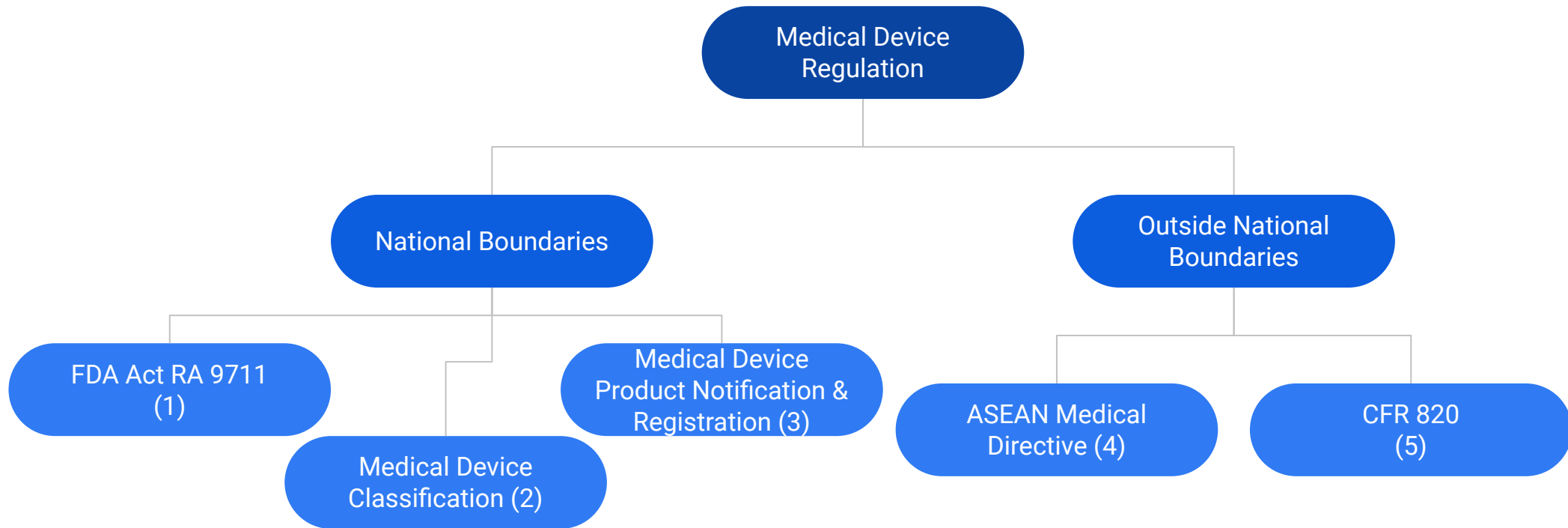# Proposed Program applied to
PQF LEVEL 8
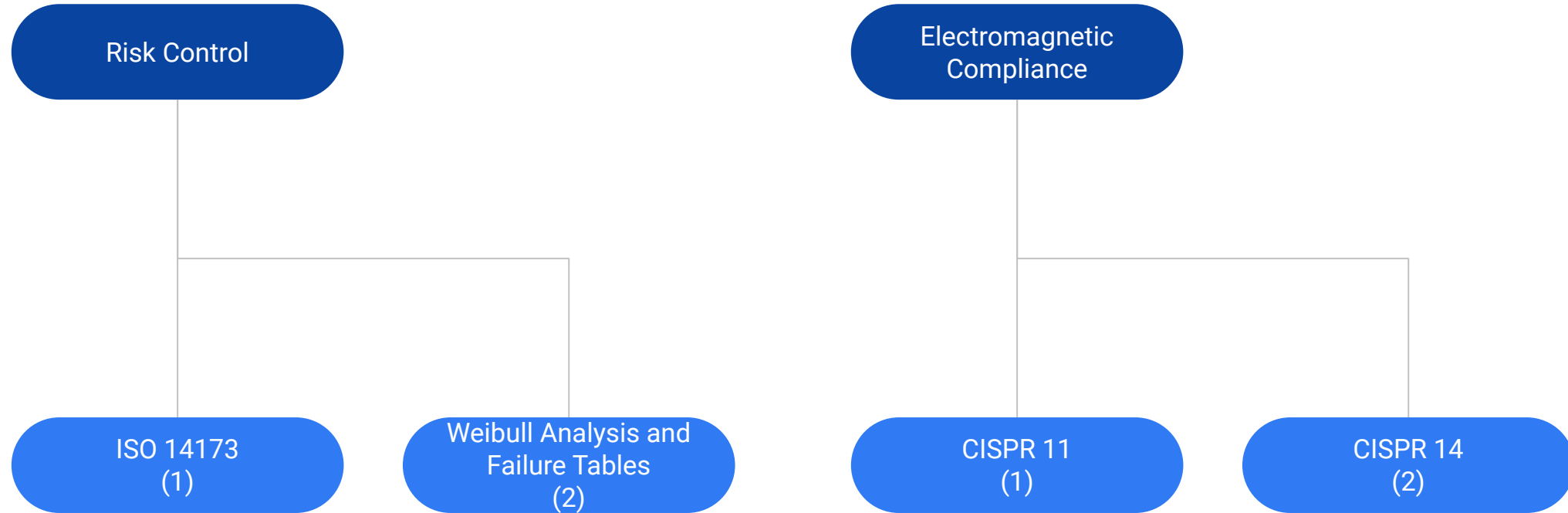
Category Breakdown for Level 8

Category Breakdown for Level 8

```
                    Quality Administration
                    System ISO 13485 as
                      a Franework (1)

          Device / Facility                    Personnel

   Quality  Health Care    Health Care Facility    Personal Qualification    Leadership (7)
   Support System (3)         Design (4)

   Clinical Engineering      Applications Training    Technical and Support    Professional Ethics
   related Information             (5.1)              Training                      (2)
   Systems (6)                                         (5.2)
```

Category Breakdown for Level 8

Category Breakdown for Level 8
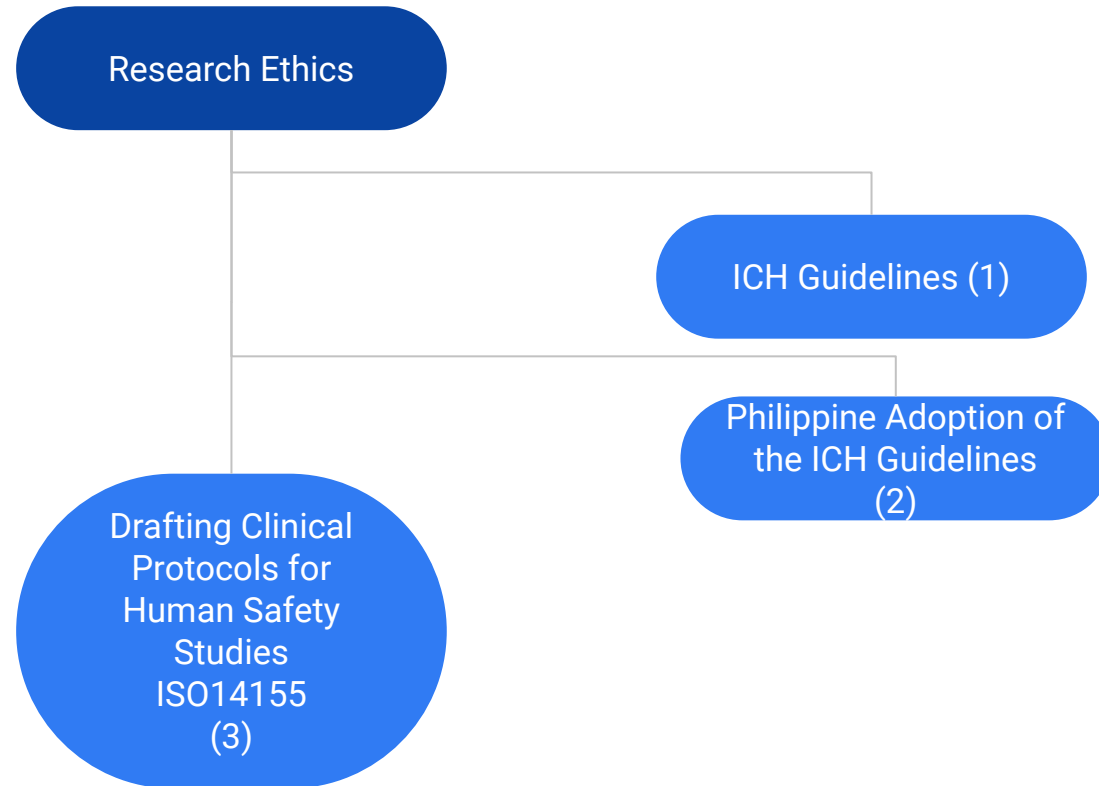
PQF 8 Proposed Training & Job Matrix

MDAP - Core 1: Medical Device Administration Program
QAS - Core 2: Quality Administration System
MDR - Core 3: Medical Device Regulation
DP - Core 4: Data Privacy
RC - Advanced 1: Risk Control
EC - Elective 1: Electromagnetic Compliance
RE - Elective 2: Research Ethics

Job	MDQP	QAS	MDR	DP	RC	EC	RE
Administer Operations	1-4	1-7	1-4	1	1-2		
Consult on New Technology	1-4	1-7	1-5	1	1-2	1-2	
Influence National Policy	1-4	1-7	1-5	1	1-2	1-2	1-2
Develop New Technology/ Concepts	1-4	1-7	1-5	1	1-2	1-2	1-3
Commercialize New Technology / Systems	1-4	1-7	1-5	1	1-2	1-2	1-3

PQF 7 Presently Training & Job Matrix

Job	MD QP	QAS	MDR	DP	RC	EC	RE
Design Electronic Systems		2					
Check / Validate Designed Systems		2					
Oversee Commissioning		2					
Provide Inspection and Upkeep Recommendations		2					

PQF 7 Proposed Training & Job Matrix

Job	MDQP	QAS	MDR	DP	RC	EC	RE
Design Electronic Systems	1-4	1-4	1	1	1		
Check / Validate Designed Systems	1-4	1-4	1	1	1		
Oversee Commissioning	1-4	1-4	1				
Provide Inspection and Upkeep Recommendations	1-4	1-4	1				

PQF 6 Presently Training & Job Matrix

MDAP - Core 1: Medical Device Administration Program
QAS - Core 2: Quality Administration System
MDR - Core 3: Medical Device Regulation
DP - Core 4: Data Privacy
RC - Advanced 1: Risk Control
EC - Elective 1: Electromagnetic Compliance
RE - Elective 2: Research Ethics

Job	MDQP	QAS	MDR	DP	RC	EC	RE
Oversee Devices/Systems							
Supervise Teams				1			
Design Control Systems				1			
Conduct Inspection and Upkeep Recommendations				1			

PQF 6 Proposed Training & Job Matrix

MDAP - Core 1: Medical Device Administration Program
QAS - Core 2: Quality Administration System
MDR - Core 3: Medical Device Regulation
DP - Core 4: Data Privacy
RC - Advanced 1: Risk Control
EC - Elective 1: Electromagnetic Compliance
RE - Elective 2: Research Ethics

Job	MDQP	QAS	MDR	DP	RC	EC	RE
Oversee Devices/Systems	1-4	2,5					
Supervise Teams	1-4	1		1			
Design Control Systems	1-4	1		1			
Conduct Inspection and Upkeep Recommendations	1-4	1		1			

PQF 5 Presently Training & Job Matrix

MDAP - Core 1: Medical Device Administration Program
QAS - Core 2: Quality Administration System
MDR - Core 3: Medical Device Regulation
DP - Core 4: Data Privacy
RC - Advanced 1: Risk Control
EC - Elective 1: Electromagnetic Compliance
RE - Elective 2: Research Ethics

Job	MDQP	QAS	MDR	DP	RC	EC	RE
Oversee Devices/Systems							
Supervise Teams							
Design Control Systems							
Conduct Inspection and Upkeep Recommendations							

PQF 5 Proposed Training & Job Matrix

MDAP - Core 1: Medical Device Administration Program
QAS - Core 2: Quality Administration System
MDR - Core 3: Medical Device Regulation
DP - Core 4: Data Privacy
RC - Advanced 1: Risk Control
EC - Elective 1: Electromagnetic Compliance
RE - Elective 2: Research Ethics

Job	MDQP	QAS	MDR	DP	RC	EC	RE
Oversee Devices/Systems	1-4						
Supervise Teams	1-4						
Design Control Systems	1-4						
Conduct Inspection and Upkeep Recommendations	1-4						

Summary

- The proposal goes beyond the limits of the stated jobs to be done by PQF Levels 8, 7 and 6.
- It defines the Qualification based on a set of jobs we expect the persons in each level to be asked to do on a normal basis.
- Broke down each job into program elements we believe that is important to execute the work.
- Created a Framework to measure knowledge, skills and abilities for each PQF.
- It is hoped that this Framework if used can help to enforce and lobby acceptance of the ECE License as an essential part of Hospital Administration based on National Policy in the same manner that ME and Civil Engineering Licenses are required under the provisions of the Office of the Building Official.