IFMBE CED White Paper
Certification/Registration of Clinical Engineering Practitioners
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1 September 2017

Glossary

AAMI: Association for the Advancement of Medical Instrumentation
AC: Administrative Council of IFMBE
ACCE: American College of Clinical Engineering
AHA: American Hospital Association
BES(UK): Biomedical Engineering Society (UK)
CE: Clinical Engineer or Clinical Engineering
CED: Clinical Engineering Division of the IFMBE and consists of a seven member board to promote clinical engineering.
CHEP: Certified Healthcare Emergency Professional
CHFM: Certified Healthcare Facility Manager
CHSP: Certified Healthcare Safety Professional
CIH: Certified Industrial Hygienist
CPHRM: Certified Professional in Healthcare Risk Management
EDMP: European Diploma of Medical Physics
EFOMP: European Federation of Organizations for Medical Physics
HTCC: Healthcare Technology Certified Commission
ICC: International Certification Commission
IFMBE: International Federation of Medical and Biological Engineering is primarily a federation of national and transnational societies representing interests in medical and biological engineering.
IMPCB: International Medical Physics Certification Board
IOMP: International Organization of Medical Physics
IRB: International Registration Board that will serve as global body for recognizing and certifying National Examining Authorities.


NEA: National Examining Authorities will establish a certification/registration program for a country and certify/register individuals.

WG: Working Group of International Federation of Medical and Biological Engineering

WHO: World Health Organization
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I. Introduction

This document is the result of a study and discussions by a IFMBE/CED Committee on Certification/Registration. The committee included the following:  
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Niranjan Khambete  
Mario Medvedec  
Frank Painter  
James Wear, Chair  
Herbert Voigt  
Ewa Zalewska

The committee has functioned with email communication and several webinar meetings. There have not been any face-to-face committee meetings.

The project initially discussed clinical engineering certification, but it was decided that registration was also a meaningful recognition of individuals having qualifications in the field. The terms “Certification” and “Registration”, therefore, will be used interchangeably in this document. Since individuals performing the clinical engineering tasks may not be engineers in all countries, the document refers to certification/registration in clinical engineering. The qualifications, however, are for performing clinical engineering tasks and not technician work. It has been recommended that the title for such individuals should be Clinical Engineering Practitioners.

Section I

II. CED Certification History

The IFMBE approved a Charter for working groups (WG) in 1979 and one was on the topic of clinical engineering. The WG members were: Ake Oberg (Sweden, Chair 1979-82), Colin Roberts (UK, Chair 1982-85), Monique Frize (Canada), Werner Irnich (West Germany), Zoltan Katona (Hungary). At the first meeting of the Clinical Engineering WG in 1980 three goals were identified:

1. to establish criteria for the mutual recognition of qualifications in the field of clinical engineering (CE). The Administrative Council (AC) approved this goal and agreed to support the work financially.
2. to publicize the field of clinical engineering through presentations at conferences and publications in journals.
3. to set-up an international network for the exchange of clinical engineering information. Only the work on the first goal is reported in this document.

The work on the first goal began with the development of the document titled: Mutual Recognition of Qualifications in the field of Clinical Engineering. The AC approved the WG budget in August 1980. The members of the WG decided to discover where CE departments existed in various parts of the world, qualifications of clinical engineers, and the role they played in health care institutions.
The WG held workshops in different countries with engineers working in hospitals. They discussed the professional role of the clinical engineers. The WG made suggestions on how the emerging profession could be recognized. They worked on developing a Certification/Registration procedure for clinical engineers in various European countries, to be locally managed by the IFMBE Affiliated Societies. Since 1973, there had been the American Association for Advancement of Medical Instrumentation (AAMI) managed certification program in clinical engineering for the US and Canada. However, there was no similar system until recently in other Societies affiliated to the IFMBE.

A draft of the document *Mutual Recognition* was sent to the Affiliated Societies in October 1980. Responses were received from the IFMBE Officers and 35% of the Affiliated Societies. In October 1981, a revised document "Agreement on Mutual Recognition of Qualifications for Clinical Engineers" was prepared and circulated to the Affiliated Societies, the majority of whom indicated their willingness in principle to sign it. This document also proposed the establishment of an International Registration Board (IRB). The following tasks were planned by the WG for 1982-5:

1. Establish a Constitution and By-Laws for the IRB.
2. Provide guidance and assistance to National Societies in the establishment of National Examining Authorities (NEA).
3. Establish criteria for the calculation of registration fees based on the principle of self-financing.

In June 1982, the IFMBE AC accepted the WG report including the proposal to establish a provisional international registration board (IRB), subject to ratification at the General Assembly later that year. The newest version of the “Agreement” document was divided into sections so that the Affiliated Societies could vote on each part separately, making it easier to reach a consensus. This amended version was presented at the IFMBE General Assembly in Hamburg, in September 1982. The Administrative Council (AC) of the IFMBE supported the WG activities, including the Registration proposal.

In 1983, the WG continued to develop a guideline for IFMBE Affiliated Societies interested in the certification project.

In recognizing the importance to the IFMBE of its development, in 1985, the WG became the first Special Division of the IFMBE and the Clinical Engineering Division was created. The members were: Monique Frize (Canada, Chair), Ake Oberg (Sweden), Dennis Hill (UK), Hannu Seitsonen (Finland), Larry Knuckey (Australia), George Broun (France), Deithart Kraft (GDR), Barry Feinberg (USA), Alf Dolan (Canada). One of the priorities of the new CED was to “help countries to start their registration/certification scheme while promoting acceptable criteria and guidelines for which a reasonable consensus had been reached.”

The CED also prepared and circulated a document titled: *Questions and Answers on how to start a Clinical Engineering Registration Program in your Country*. Dennis Hill of the UK compiled suggestions from the CED Board members and consolidated these into a document titled: *Topics to be studied as part of the IFMBE Certification Schemes for clinical engineers*.

In 1986, the CED continued to work on Registration and criteria for qualifications for clinical engineers. Dennis Hill proposed a Clinical Engineering Certification Scheme to the Biomedical Engineering Society (UK) that would start to operate in October of the same year. Hill also developed an application form for clinical engineers who wished to apply in the UK. This forward
move was to be a model for other countries to replicate, if they were willing, as the foundation for a successful development was available.

In 1987, the CED reaffirmed that the CED role was to be a source of information for countries wishing to set-up their own Registration process. The plan was to collect information on existing processes in various countries. Countries could then select the model that best fitted their needs and adapt it for their local programs.

In 1988, at the March meeting there was a review of the document on Mutual Recognition. The “Mutual Recognition of Qualifications for Clinical Engineers” 1989 document is in Appendix B.

As of 1990, the original aim to achieve mutual recognition of qualifications between member countries had yet to be achieved.

From 1991 through 2000, there appears that nothing further was done by the CED with regard to certification/registration.

In 2005, Dr. Joachim Nagel, then president of IFMBE, brought together a group of clinical engineers in Stuttgart, Germany. One of the purposes of this group was to update the “Agreement on Mutual Recognition of Qualifications for Clinical Engineers.” One of the documents drafted from this meeting was “The IFMBE International Register of Clinical Engineers” which was the update is Appendix C. This document was apparently not approved at any level in the IFMBE.

In July 10, 2010, IFMBE/CED Chairman, Yadin David issued communication to the board of the need for IFMBE to lead the global CE credentialing effort and suggested that funding and the creation of a task force to be led by Professor Mario Medvedec will increase the potential for successful implementation. Following that, IFMBE work on certification/registration of clinical engineers was started with an IFMBE/CED project 2013/15 led by Mario Medvedec. This project has continued in 2016/18 with James Wear as the project leader.

III. Definition of Clinical Engineering

There are several definitions of clinical engineering, but all have similar roles. Here are the most common definitions.

“A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.” ACCE definition, 1992

“Clinical engineering is taken to mean the application of medical and biological engineering within the clinical environment, for the enhancement of health care.” IFMBE, Nagel document, 2005

“Clinical Engineer (CE) A professional who is qualified by education and/or registration to practice engineering in the health care environment where technology is created, deployed, taught, regulated, managed or maintained related to health services. Other related terms used for the CE role in developing countries include biomedical engineer, and rehabilitation engineer. (Clinical Engineering Global summit 2015, http://global.icehtmc.com/)."
Clinical engineering practitioners may be Healthcare Technology Managers, Clinical Engineering Technologists and Clinical/Biomedical Engineering Technicians who are technology managers at some levels.

IV. Role in Clinical Engineering

The role in Clinical Engineering to be considered as qualified for the years of practice should include most of the following areas: (These are expanded in the IFMBE document in Appendix C)

1. Advisory Service on Available Technology
2. Consulting on the Evaluation and Purchase of Medical Equipment
3. Planning and Supervising the Maintenance of the Medical Equipment
4. Obviating Hazardous Situations with Medical Equipment and its use
5. Aiding in the Interpretation of the Measurements of Medical Devices
6. Providing Engineering Competence to the day-to-day technical support and facilities of the medical institution.
7. Provide Education to the Clinical Engineering and Clinical staff with regard to the Medical Devices and their use.
8. Support Research and Development of medical devices and technology in healthcare delivery.

There is also the clinical engineering technologist which in many cases may perform the same functions as the clinical engineer. In fact, the higher level clinical engineering technician or biomedical engineering technician may also perform some of the functions of the clinical engineer even in the US.

V. Potential for Clinical Engineers to become certified who live in Countries/regions with no existing certification program.

The IFMBE CED could develop a program or encourage other existing regional programs to certify individuals from countries that do not have a certification/registration program, but it would have to be something that could be continued. This program would require a permanent secretariat to maintain records, remind individuals of the renewal information, process applications, coordinate review by a certification committee established by the IFMBE CED.

It appears that it would be most practical for this to be certification-by-credentials only, so exams would not have to be developed and security was not a major concern. The problem of providing exam-venues would also be avoided. Individuals would more likely be able to have credentials produced in English than to take and pass exams in English.

The cost for each applicant would have to be sufficient to support the program. There would need to be a renewal process at least every three years with forms and a fee. It appears that the minimum fees should be $100 US for initial application and $25 US per year for renewal or $75 US every three years.

This would require a committee of 3-5 certified/registered individuals to evaluate the applications initially and the renewals. This should be a voluntary function.
Once a country/region develops a certification/registration program, individuals from that area would no longer be certified by this program.

A program has been established for medical physicists that can address the problem they might have with no certification in their own country. The European Federation of Organizations for Medical Physics (EFOMP) has developed a program for medical physicist’s certification that allows them to work in different European countries. (https://www.efomp.org/index.php?r=pages&id=eeb-about). The EFOMP’s Examination Board (EEB) introduces the European Diploma of Medical Physics (EDMP) and the European Attestation Certificate to those Medical Physicists that have reached the Medical Physics Expert level (EACMPE). The EDMP will facilitate mobility of medical physicists in Europe and beyond.

VI. ISO/IEC 17024:2012 Conformity assessment – General requirements for bodies operating certification of persons
   https://www.iso.org/standard/52993.html

In 2012 a new international standard was developed to harmonize the various procedures used around the world for certifying the competence of personnel in different occupations or professions. The NEAs for certification/registration programs in clinical engineering should work toward meeting this standard.

This updated ISO/IEC 17024:2012 standard will help NEAs that certify/register individuals in clinical engineering protect the integrity and ensure the validity of the programs. It will also promote public confidence in the capabilities and competence of the people who provide the certification/registration.

The standard addresses the structure and governance of the certifying body, the characteristics of the certification program, the information required to be available to applicants, and the recertification initiatives of the certifying body. It is designed to help organizations conduct well-planned structured evaluations in order to ensure impartiality of operations and reduce any conflict of interest.

The Healthcare Technology Certification Commission (HTCC) in the United States is studying this standard to see where it is not in compliance. It is then determining what is necessary to come within compliance. HTCC has not yet decided if it will make an application to be accredited by the standard.
Section II

VII. Recognition or Certification of Certification/Registration Programs in Clinical Engineering

International Registration Board for Certification/Registration in Clinical Engineering

The IFMBE/CED can establish an International Registration Board (IRB) that will serve as global body for recognizing and certifying National Examining Authorities (NEAs). It is not practical for the IFMBE/CED to try to register all individuals that NEAs have certified/registered. An operation to have an up-to-date register of several hundred individuals certified/registered in clinical engineering would require an on-going administrative staff. It would require continued updating of files as individual’s certification/registration are renewed or otherwise change.

Certifying only the NEAs would only require minimal administrative time and probably could be done by the CED Secretary. Presently, there would be less than ten programs recognized/certified if all of the existing programs chose to do so. It would be required to maintain the programs contact on the CED website and to maintain the files for programs that are certified. Annually the certified programs should submit a report on the numbers certified/registered including renewals and any program changes made.

This IRB might include other members in addition to CED Board members. A member of each NEA that is certified could be a member. WHO might have a member. Most of the members of the IRB should be certified/registered in clinical engineering.

The IRB will establish a committee to review requests for a certification/registration program to be recognized/certified by the CED.

Requests for recognition/certification of a NEA must be submitted in English with a contact person. The request must include the following:
- A Contact Person
- Detailed Program Description
- Date Program was established
- Sponsoring Organization (Stand alone, Professional Organization, Government Entity)
- Number of people Certified/Registered
- Board Members
- Relevant Documents (By-Laws, Ethics, Marketing, etc.)

NEA By-Laws: describes the structure of the NEA, the rules for election, the mandate term, the connection or independence to an association, the profile of the candidates for the board of examiners and so forth.

Code of Ethics: where it is described the way certified/registered individual should behave professionally. An IFMBE example and an example from Canadian Medical and Biological Engineering Society are in Appendix D.

Method for renewal of the Certification: defines the procedure to be followed for the renewal of the Certification. Four years should be the maximum validity for the certification since the
knowledge base for a CE in their area always should be updated; the actual time should be optional for each NEA.

Candidate handbook: This sets the rules and minimum qualifications for a professional to apply for certification/registration; his/her minimum academic background and professional experience and if there are exams. The structure of any examination (written and/or oral) and the grades attribution for each kind of examination (if more than one) should be provided.

After review by the IRB committee, a recommendation will be made to the IFMBE CED Board. The CED Board can vote to accept the program for certification/recognition, reject the program or return to the committee for additional information. The CED Board decision will be provided to the sponsoring organization which will be notified through the contact person.

If the program is accepted for certification/recognition, the program description and contact person will be added to the CED website.

Every change in the NEA’s requirements and procedures for the certification process and changes of the board members or contact person should be reported to the CED/IRB.

The CED international recognition can be withdrawn in case of proven violations of Policies 1.2, 1.3 or 1.4 established below in Policies.

The program will be reviewed every 5 years to determine if it still exists. A renewal application will not be required. If the program no longer exists it will be dropped from the CED website.

If a dropped program is reestablished, a new request for certification/recognition will be required.

VIII. Some Recommendations for initiating New Certification/Recognition Programs in Clinical Engineering.

A new certification/registration program can be initiate by a government agency such as the Ministry of Health, a professional organization such as a national biomedical or clinical engineering organization or by an organization just to do the certification/registration. The most critical step is getting a small group of people who are interested in the project and willing to work on it. Several attempts have been made to initiate certification programs which have never gone forward because not enough people were willing to work on it or due to lack of agreement on candidates’ qualifications.

How to Establish a Certification/Registration in Clinical Engineering

The first step in establishing a certification/registration program in clinical engineering in a country or region is to set up a National Examining Authority (NEA). This would be basically the same process for a program with exams or one based solely on credential review.

A professional society or other similar organization is a good start for recognizing the need for and support of the certification/registration program. They then can establish a committee to start developing the initial setting-up procedure, including the designation of the initial board members.
This committee should be made up of recognized senior clinical engineers, whose qualifications and credibility are accepted by most of the people in the clinical engineering field in the country/region. Some of the members may be non-practicing clinical engineers such as academic or medical personnel.

The first group to form the NEA should be grandfathered based on their credentials if practicing clinical engineers. This was done in the United States, Canada and Taiwan when their programs were started. In fact, for the first year in these three programs, there was a “peer review” with no examinations or interviews by the first NEA. The people selected for certification/registration in these programs had a long standing in clinical engineering; which was important for the credibility of the programs.

The “peer review” for the first NEA for a new program could be done by the members of the IFMBE/CED. This would be a useful way to launch programs in countries by a “standardized” approach, review and recognition process.

The first tasks of the NEA should be:
1. To make an analysis of the cost of the program; the variables affecting the costs are:
   - the number of NEA meetings to be held per year;
   - the geographical distance to be covered and cost of travel to attend meetings
   - the number of members on the NEA
   - and if a separate board of clinical engineer examiners is used

The variable affecting the revenue is:
   -the number of potential candidates to be certified/registered. The larger the number of candidates, the more income that can be applied against the costs of running the program.

2. The NEA should establish a constitution and by-laws and the certification/registration procedure to be developed. This includes the examination board members and procedures such as the application review, examination (if used) and interviewing methods.

**Recommended Guidelines for the establishment of National Examining Authority**

1. Policies:
   1.1 The NEA will be a unit of a professional society, of a government unit or of some other professional unit.

   1.2 The NEA shall not endorse any commercial enterprise.

   1.3 Neither the name of the NEA nor the name of any of its members in their official capacities shall be used in connection with a commercial company.

   1.4 Members of the NEA shall not receive any money or gifts for any function of the NEA other than stipends covering expenses directly involved in certain NEA activities. Members should be subject to ethical norms and agree to maintain NEA confidentiality.

2. Membership:
   2.1 Membership of the NEA shall be invited certified/registered clinical engineers or other suitable persons. (The first clinical engineer members could be certified/registered by “peer” review or “grandfathered”)

2.2 Membership shall be by invitation from the NEA only

2.3 Any member may resign their position on the NEA by written request to the Chairperson of the NEA and acceptance by the majority of the NEA.

2.4 The initial clinical engineer membership of each NEA will be certified/registered by “peer review”. This may be by members of the IFMBE/CED board.

3. Composition of the NEA:
3.1 The NEA shall consist of not less than 5 members, with consideration for specifications in paragraph 5.1.

3.2 The NEA, when considering candidates, shall strive for a harmonious group representing major areas of specialization and representing diverse geographical locations and languages as appropriate.

4. Petitioning for Membership
4.1 Any interested person may petition the NEA for consideration for membership.

4.2 Any member of the NEA may suggest individuals for consideration for membership.

4.3 Any candidate for consideration of membership of the NEA must submit a resume to the Chairperson of the NEA. A copy of that resume shall be made available through the NEA Secretariat to each member of the NEA before the pertinent election.

4.4 Membership of the NEA shall be limited to those candidates who have won approval of the majority of the current members of the NEA. Approval shall be by vote by NEA meeting, email or regular mail.

5. Tenure of Membership of the NEA
5.1 Tenure of the membership of the NEA can be up to 3 years. In special circumstances, it could be extended especially when the number of qualified potential members is very limited.

5.2 NEA members can serve more than 3 years, but not normally consecutive terms (see paragraph 5.7)

5.3 An ex-member may be re-nominated after a 3-year hiatus from membership.

5.4 Any member of the NEA may be requested to resign for just and due cause after a two-thirds vote by the NEA for such removal.

5.5 A member of the NEA will automatically lose membership if they are absent without permission from two consecutive annual meetings of the NEA.

5.6 A member of the NEA will automatically lose membership if they fail to respond to three written NEA actions initiated by the Chairperson or sponsored by two members.

5.7 The chairperson’s term shall be two years which may be in addition to whatever period that person may have served as a member of the NEA.
5.8 After completion of their term, the Chairperson may not serve on the NEA (unless they need to complete their three year term) until after a three-year hiatus.

5.9 During the first two years of operation, the tenure of the NEA members shall be staggered to provide a continuity of experience.

6. Officers of the NEA.
6.1 The officers of the NEA shall be elected by a two-thirds vote of the NEA. The officers shall normally consist of a Chairperson and deputy Chairperson.

6.2 All matters of business related to nomination and election of officers for which provisions are not specially included in these guidelines shall be resolved as all other regular matters of the NEA business except that a two-thirds vote shall be required.

6.3 Each NEA will appoint a Secretary designated to provide the services of taking minutes of the meetings and assisting the Officers with the maintenance of records and correspondence arising from the conduct of business matters of the NEA. The Secretary is not a member of the NEA.

7. Committees:
7.1 Committees may be appointed for purposes designated by the Chairperson and approved by the NEA.

7.2 All committees shall keep accurate minutes of the meetings and make progress reports to the Chairperson.

8. Meetings:
8.1 The Chairperson shall preside over all meetings, as practicable.

8.2 The Deputy Chairperson shall preside at meetings in the absence of the Chairperson.

8.3 Annual meetings shall be in conjunction with a national society major meeting.

8.4 Other meetings may be physical, teleconference, webinar or by other technology.

8.5 The agenda for each meeting shall be sent to each member of the NEA at least 30 days prior to the meeting by mail or email.

8.6 Special meetings may be called by the Chairperson or by any three members of the NEA by notifying all members of the NEA at least 60 days prior to the meeting date and sending an agenda in accordance with para 8.4.

8.7 A quorum exists if more than one-half of the members of the NEA are present in person.

8.8 The agenda shall prevail for order of business.

8.9 Modification of the agenda shall be allowed at the opening of the meeting.

8.10 The meeting of the NEA shall be conducted informally with the participation of all members present. The latest revision of Roberts’ rules of order shall be imposed at the discretion of the
Chairperson or any two members of the NEA. Meeting minutes shall be maintained within the NEA files.

9. On-going Business of the NEA
9.1 The NEA shall transact business throughout the year by use of mail, email and telephone.

9.2 To conduct a vote by mail or email, the Chairperson shall prepare a ballot, posing the question in a non-biasing fashion as to allow a Yes-No response. The ballot will be such that the member need only mark an X in the appropriate box and return the ballot.

9.3 Each member of the NEA shall have a single vote on all matters.

9.4 The Chairperson shall not vote on any matter except to break a tie.

9.5 Except where otherwise specified, all matters presented to the NEA shall be resolved by a majority vote at a meeting at which a quorum is present.

The next step is to determine what type of program that is to be initiated. The following options have been used to initiate existing programs:
- Certification by exam
- Certification by Credentials initially and then exams
- Certification or Registration by Credentials only
- Certification by proxy (valid certificate from another program acceptable to NEA).

All four of these approaches have the issue of needing an initial group who will develop an exam or evaluate credentials. This means obtaining the initial help of individuals from existing certification/registration programs or having a small group of very experienced individuals who will evaluate each other’s credentials. Both methods have been used to initiate existing programs. This may be the NEA members or a separate Board of Examiners.

**Examples of Certification Systems created around the world**

In the US, the American Board of Certification (one of the two original certification programs) was started by 5 academic individuals certifying each other and they developed exams for all other applicants. This group was merged with the AAMI program in 1985 when the International Certification Commission was created. In the State of Texas, for a similar period, a professional engineer could be registered in the biomedical engineering practice area.

At the same time, a few experienced hospital clinical engineers in AAMI certified each other and formed a committee to certify any others that applied in the first year. This became the AAMI/ICC program, which was discontinued in 1999.

The current Healthcare Technology Certification Commission (HTCC) was created in 2002 to initiate the current certification program. They established a Board of Examiners from people who were certified in the AAMI/ICC program. This group then accepted any one certified under the AAMI/ICC program that submitted an application similar to a renewal application for a period of one year. The board developed exams for all new applicants.
The Taiwan Society for Biomedical Engineering developed a Clinical Engineering Certification program in 2000 and certified applicants based on credentials until they gave their first exam in 2007.

The Chinese Clinical Engineering Certification program was developed by using individuals certified by HTCC to develop exams and the oral exams to be given by these individuals. This is still being used.

Registration programs in Ireland and South Africa are based on credentials evaluated by a group of registered individuals.

A discussion of all known certification/registration programs is in Chapter 4 of the WHO “Human Resources for medical devices, the role of biomedical engineers” in Appendix E.

IX. Certification/Registration by Credential Review

Some programs may choose to certify/register individuals in clinical engineering by credential review only instead of exams. This is almost always true for registration and is the manner that the initial individuals on a National Examining Authority can be certified/registered. This section is an example of how this process can be used. Individual societies may want to make modifications to the process to take into account how clinical engineering is practiced in their country or region.

1. Qualifications:

A: Education:
The applicant must normally hold at least a bachelor degree level in engineering or some related technical/scientific field. They should also have some continuing education to demonstrate they are continuing to keep up in the field. The continuing education can be meeting attendance, short courses, on-line material or reading journals and books.

B: Experience:
They should have 3-5 years of responsible full-time work in the field of clinical engineering. This should be documented with titles and responsibilities for these years and verified by their employer.

Professional participation in biomedical/clinical engineering societies and other relevant societies should be documented. Any offices or committee work is important as experience.

All presentations and publications including those at professional meetings, in recognized journals, in local and in-house venues should be documented.

Any other certifications, licenses, awards or honors should be documented.

C. References:
The applicant should have submitted three letters of reference by other engineers, medical staff or administrative staff including examples of the clinical engineering work. These letters must address the applicant's professional reputation for competence, judgement, integrity and ethics.
D. Current position:
Applicant must submit a current official position description and the institution organization chart that indicates where their position is located.

2. Application:
An application form is needed to fill in the qualifications. This form might include points for each item to aid in the evaluation of the application.

The applicant must also submit a detailed current CV or resume.

The applicant must also provide information on the individuals who will be submitting letters of reference. These letters should be submitted directly to the Secretariat of the NEA and not through the applicant.

3. Evaluation and Recommendations
At least two members of the NEA will review the application and make a recommendation with comments to the entire NEA.

The NEA could have an oral interview as part of the evaluation. This could be done by Skype or similar technology methods or in person. This would be an interview and not an oral exam.

The full NEA would vote on an applicant’s certification/registration. The applicant will be informed of the NEA decision through the Secretariat.

4. Appeals
Candidates should direct appeals through the Secretariat. Appeals are to contain information not previously presented or information that clarifies a point.

The Secretariat shall direct each appeal to the NEA for review. The NEA shall decide by majority vote, whether the candidate’s appeal is valid or not. The decision of the NEA shall be reported to the candidate through the Secretariat.

X. Certification by Examination
If the NEA decides to do certification by examination, the following process is an example that can be followed. This will be after the initial NEA membership is established and no one will be “grandfathered” based on credential review.

1. Qualifications:
   A: Education:
   The applicant must normally hold at least a bachelor degree level in engineering or some related technical/scientific field. They should also have some continuing education to demonstrate they are continuing to keep up in the field. The continuing education can be meeting attendance, short courses, on-line material or reading journals and books.
B. Experience:
They should have 3 years of responsible full-time work in the field of clinical engineering. This should be documented with titles and responsibilities for these years and verified by their employer.

Professional participation in biomedical/clinical engineering societies and other relevant societies should be documented. Any offices or committee work is important as experience.

All presentations and publications including those at professional meetings, in recognized journals, in local and in-house venues should be documented.

Any other certifications, licenses, awards or honors should be documented.

C. References:
The applicant should have submitted three letters of reference by other engineers, medical staff or administrative staff including examples of the clinical engineering work. These letters must address the applicant’s professional reputation for competence, judgement, integrity and ethics.

2. Application
An application for certification in clinical engineering is first directed to the NEA Secretariat. The Secretariat will obtain the applicant’s references and forward the application and references to the NEA.

The application will be reviewed by at least two NEA members who will make recommendations and comments to the entire NEA. The complete NEA will decide whether or not the applicant should undertake a written test and/or be interviewed.

If the NEA does not recommend testing, the application is denied, and the applicant is informed of the decision. If a candidate is lacking sufficient experience or specific academic preparation, a maximum period of one year will be given to present proof that the deficiency no longer exists. The applicant will be allowed to proceed to the exam if the deficiency is amended within the one-year period.

At this point, the applicant may choose to follow the appeal procedure outlined below. The applicant is given an opportunity to respond through the Secretariat to the specific reasons for the denial. The applicant’s response is forwarded through the Secretariat to the NEA for consideration.

3. Exam:
The written examination should be designed to test the candidate’s clinical engineering knowledge. The questions for the exam should be developed by the NEA members and the exam maintained with high security.

Upon successful completion of the written examination, a candidate may take the oral exam. Certification will not be recommended if the candidate does not pass the written exam.

The purpose of the oral exam is to determine the candidate’s depth and breadth of clinical engineering experience. During the oral exam the candidate’s professional ability to make engineering value judgements is evaluated.
The oral exam is conducted by a minimum of two interviewers. Each interviewer returns to the NEA, through the Secretariat, written comments on the exam regarding reasons why the candidate should or should not be recommended for certification.

In all cases, the majority decision of the NEA will decide whether a candidate will be certified. If the candidate is not recommended for certification, the candidate may follow the appeals procedure.

4. Appeals:

Candidates should direct appeals through the Secretariat. Appeals are to contain information not previously presented or information that clarifies a point.

The Secretariat shall direct each appeal to the NEA for review. The NEA shall decide by majority vote, whether the candidate may be tested or retested, or whether the appeal should be evaluated further at the next meeting of the full NEA. The decision of the NEA shall be reported to the candidate through the Secretariat.
APPENDIX A

Other Healthcare Related Certification Programs

In the Healthcare field, there are many certification/registration programs. Most of the programs are relevant to the patient care staff such as physicians, nurses and clinical technicians. In many cases, these individuals must have the certification/registration to have jobs at least at the upper levels.

However, there are some certifications that are not required in all healthcare facilities to maintain a job. These certifications are in fields that are technical like clinical engineering and most are in the United States. A brief description of each of these programs is included here for comparison to clinical engineering certification/registration programs.

Certified Healthcare Facility Manager
http://www.aha.org/certifcenter/CHFM/index.shtml

The Certified Healthcare Facility Manager (CHFM) is the program that is the most similar to clinical engineering. The American Hospital Association (AHA) is responsible for the CHFM certification supported by the American Society for Healthcare Engineering. The CHFM certification program promotes healthcare facility management through certification of qualified individuals who meet the eligibility requirements and pass the CHFM Examination. CHFM certification renewal is required through continued personal and professional growth in the practice of healthcare facility management. AHA provides a national standard of requisite knowledge required for certification; thereby assisting employers, the public and members of health professions in assessing healthcare facility managers.

The requirements to take the certification exam require fulfilling one (1) of the following requirements:
• Baccalaureate degree from an accredited college or university plus three (3) years of associated engineering experience*, three (3) years of which must have been in a healthcare setting; and including three (3) years of management/supervisory/administrative experience in a healthcare setting.
• Associate degree from an accredited college or university plus five (5) years of associated engineering experience*, three (3) years of which must have been in a healthcare setting; and including five (5) years of management/ supervisory/administrative experience in a healthcare setting.
• High school diploma or equivalent plus seven (7) years of associated engineering experience*, three (3) years of which must have been in a healthcare setting; and including five (5) years of management/supervisory/administrative experience in a healthcare setting.

*Associated engineering experience refers to work experience in the following functional areas: facility management; operations and maintenance; clinical engineering; safety and security; planning, design and construction; or environmental management.

There are about 2000 individuals certified as CHFM and hospitals frequently request this in ads for new facility directors.
Definition of a Healthcare Facility Manager:

The healthcare facility manager’s primary job responsibilities include the following general areas:
- Maintenance and Operations
- Code Compliance
- Planning, Design and Construction
- Finance Management
- Administration

Specifically, the healthcare facility manager has an understanding of the operation and maintenance of building systems including but not limited to the following:
- HVAC
- Electrical distribution
- Medical equipment
- Refrigeration
- Emergency power
- Safety and security
- Steam and hot water
- Fire protection
- Elevators and pneumatic tube
- Medical gas
- Plumbing
- Grounds keeping

The healthcare facility manager’s responsibilities may include the following:
- Planning, design and direction of activities related to construction and renovation projects. These activities include but are not limited to solicitation and evaluation of bids and consulting with architects, engineers and various contractors.
- Facility conformance to all applicable codes and standards including local and federal agencies as well as private certification organizations.
- Development and management of capital and operational budgets and negotiation of service agreements.
- Development and administration of policies and procedures to manage the human resources of the facilities management department.

Certified Professional in Healthcare Risk Management
http://www.aha.org/certifcenter/CPHRM/index.shtml

The Certified Professional in Healthcare Risk Management (CPHRM) is another program that the American Hospital Association (AHA) is responsible for. The CPHRM certification program promotes healthcare risk management through certification of qualified individuals who meet the eligibility requirements and pass the CPHRM Examination.

CPHRM certification renewal is required through continued personal and professional growth in the practice of healthcare risk management. AHA provides a national standard of requisite knowledge required for certification; thereby assisting employers, the public and members of health professions in assessing healthcare risk managers.

The requirements to take the certification exam require fulfilling one (1) of the following requirements:
• Baccalaureate degree or higher from an accredited college or university plus five (5) years of experience in a healthcare setting or with a provider of services to the healthcare industry.
• Associate degree or equivalent from an accredited college plus seven (7) years of experience in a healthcare setting or with a provider of services to the healthcare industry.
• High school diploma or equivalent plus nine (9) years of experience in a healthcare setting or with a provider of services to the healthcare industry.

Risk Management Experience • 3,000 hours or 50 percent of full-time job duties within the last three years dedicated to healthcare risk management in a healthcare setting or with a provider of services (e.g. consultant, broker, or attorney) to a healthcare facility.

Definition of a Healthcare Risk Management Professional

The Healthcare Risk Management Professional's primary duties include the prevention, reduction, and control of loss to the healthcare organization, its patients, visitors, volunteers, physicians, other healthcare professionals and employees. Regardless of the healthcare delivery system in which the individual works, the Healthcare Risk Management Professional interfaces with a number of healthcare professionals in the accomplishment of these objectives. Duties may include incident investigation and analysis, tracking, trending and evaluation, risk financing and claims management.

Certified Healthcare Safety Professional (CHSP)  
http://ibfcsrm.org/chsp.php

The International Board for Certification of Safety Managers (IBFCSM) was established in 1976 as a not-for-profit independent credentialing organization. The Board established certification and re-certification requirements for the Certified Healthcare Safety Professional (CHSP) in 1978. The Board operates as an independent professional credentialing organization that is not affiliated with any other membership group, association, or lobbying body. The Board exists solely for issuing individual certifications to qualified candidates. Their mission is to 'Upgrade the Profession' by offering real world and practical certifications.

The CHSP credential was established to focus on the importance of using management principles to improve the safety performance of healthcare organizations. Since 1978, the Board has issued more than 3,200 CHSP credentials. The broad scope of the CHSP Exam attracts applicants from various healthcare backgrounds including, but not limited to, safety, security, infection prevention, employee health, nursing, quality improvement, administration, risk management, facility management, plant operations, hazardous materials management, emergency management, life safety, biomedical services, environmental services, laboratory operations, nursing homes, surgery centers, insurance loss control, and safety consulting. The CHSP credential continues to attract applicants desiring to improve their professional practice in healthcare safety and related functions. Earning the CHSP credential provides recognition and documents achievement. The CHSP designation is one of more than 30 acceptable academic/professional designations for applicants to hold when seeking the Distinguished Fellow -DFASHRM or Fellow - FASHRM recognition of the American Society for Healthcare Risk Management (ASHRM). The CHSP is also recognized by the state of Pennsylvania. Healthcare organizations which need certified professionals that understand how proactive safety practice supports operational effectiveness, improves care processes, and reduces organizational costs.
Candidates are not required to have a four-year degree to qualify. IBFCSM issues credentials at the Master and Associate Levels. Master Level Candidates must document relevant experience and/or college education to equal eight (8) years. Master Level Candidates must document four (4) years of experience regardless of education. Associate Level Candidates must document four (4) years of experience and/or education combined with a minimum of two-years of experience. Thirty (30) semester hours of college credit equals one year of experience. Official college transcripts are not required unless specifically requested by IBFCSM. College credits and degrees must be earned from Regionally Accredited Institutions.

Each exam contains at least 100 multiple choice questions with four possible answers. Exam content is developed with assistance of practicing professionals and/or subject matter experts. IBFCSM statistically analyzes exams to ensure both validity and reliability.

Certified Healthcare Emergency Professional (CHEP)
http://ibfcsm.org/chep.php

The Certified Healthcare Emergency Professional (CHEP) is another certification established in 2008 by the International Board for Certification of Safety Managers (BCHCM). The Board establishes certification and re-certification requirements for the Certified Healthcare Emergency Professional (CHEP). The Board operates as an independent professional credentialing organization that is not affiliated with any other membership group, association, or lobbying body. The Board exists solely for issuing individual certifications to qualified candidates. Our mission is to 'Upgrade the Profession' by offering real world and practical certifications.

The Board developed the CHEP credential to meet a need for a practical but 'professional certification' for healthcare emergency directors, managers, coordinators, associates, consultants, and others who work with or coordinate real world issues with the health sector. The program relies on information, standards, and best practices from reliable sources including organizations such NFPA, ASTM, DHS, EPA, OSHA, FEMA, and accrediting organizations such as the Joint Commission. Healthcare organizations need professionals that understand how emergency management principles support the healthcare environment of care, the local community, and the nation.

Candidates are not required to have a four-year degree to qualify. IBFCSM issues credentials at the Master and Associate Levels. Master Level Candidates must document relevant experience and/or college education to equal eight (8) years. Master Level Candidates must document four (4) years of experience regardless of education. Associate Level Candidates must document four (4) years of experience and/or education combined with a minimum of two-years of experience. Thirty (30) semester hours of college credit equals one year of experience. Official college transcripts are not required unless specifically requested by IBFCSM. College credits and degrees must be earned from Regionally Accredited Institutions.

Each exam contains at least 100 multiple choice questions with four possible answers. Exam content is developed with assistance of practicing professionals and/or subject matter experts. IBFCSM statistically analyzes exams to ensure both validity and reliability.
The American Board of Industrial Hygiene has issued certificates to Certified Industrial hygienist (CIH) since 1960. The number issued is about 12,000. This program is accredited by ISO/IEC 17024:2012.

A Certified Industrial Hygienist (CIH) is an individual who has met the minimum requirements for education and experience, and through examination, has demonstrated a minimum level of knowledge and skills in the following rubric (subject matter) areas:

- Air Sampling & Instrumentation
- Analytical Chemistry
- Basic Science
- Biohazards
- Biostatistics & Epidemiology
- Community Exposure
- Engineering Controls/Ventilation
- Ergonomics
- Health Risk Analysis & Hazard Communication
- IH Program Management
- Noise
- Non-Engineering Controls
- Radiation – Ionizing and Non-ionizing
- Thermal Stressors
- Toxicology
- Work Environments & Industrial Processes

Once the CIH credential is obtained, the Diplomate can apply their knowledge in many different situations, some broad scope and comprehensive, some narrow scope as the person specializes. The domains of practice often differ and change many times during the course of a career. Thus, ABIH places no restrictions or qualifications on the career paths of a CIH as long as the person meets the on-going requirements in the certification maintenance program and adheres to the professional, enforceable Code of Ethics.

To be eligible to sit for the CIH exam, someone needs to show that they have met specific standards for both formal education and professional IH experience. The criteria need to include all the following:

Possess at least a 4-year Bachelor’s Degree from a regionally-accredited college or university:
- in Biology, Chemistry, Physics, or Engineering, or
- in IH or Safety from an ABET-accredited program, or
with at least 60 semester hours of science, math, engineering, or science-based technology (15 hours at the junior, senior, or graduate level).

Have completed at least:
- 180 academic contact hours* or 240 continuing education contact hours of IH coursework with at least half of those hours in the areas of Fundamentals of IH, Toxicology, Measurements and Controls
• 2 hours of ethics training or coursework

Have professional level, broad-scope IH experience spanning:
• at least 4 years of IH practice (1 year or 6 months of credit available for graduates of an ABET-accredited IH program, with a master’s or bachelor’s degree respectively), and at least two of the following occupational health stressors: chemical, physical, biological or ergonomics

Need to provide at least two written confidential questionnaires from:
• current supervisor to verify current level of IH work
• all other supervisors verifying all other work experience periods claimed
one CIH who is familiar with your work experience (alternatives are available)

International Medical Physics Certification Board
http://www.impcbdb.org/about/

The International Medical Physics Certification Board (IMPCB) was formed on May 23rd, 2010 by eleven Charter Member Organizations in medical physics. The objectives and purposes:

• To support the practice of medical physics through a certification program in accordance with International Organization of Medical Physics (IOMP) guidelines;
• To establish the infrastructure, requirements and assessment procedures for the accreditation of medical physics certification programs in accordance with the requirements of IOMP guidelines;
• To establish the infrastructure, requirements and examination procedures for the certification of medical physicists in accordance with the requirements of IOMP guidelines;
• To provide guidance and support to medical physics organizations for the establishment of national medical physics certification boards and to conduct board examinations for medical physicists in countries which have not yet established certification boards;
• To grant and issue certificates in the field of medical physics to applicants who have been found qualified by the Board;
• To maintain a registry of holders of such certificates, which can be accessed online free-of-charge by the IOMP, and to serve the public by preparing and furnishing lists of medical physicists who have been certified by the Board; and
• To establish that continuing education and professional development are required for certified medical physicists.

A Model for the Medical Physics Certification Process

The following minimum requirements should be required of candidates who wish to take the three-part Board examinations.

Part I Written Examination (General Medical Physics)
• Education – graduation from an accredited college or university with an advanced degree (Masters or Doctorate) in physics, medical physics or an equivalent degree in an appropriate physical or engineering science discipline.
• Professional Training – none required

**Part II Written Examination (Medical Physics Specialty)**
• Education – requirements as specified above for Part I
• Professional Training – 2 (two) years full-time equivalent training preceding the date of application for examination. The training should be carried out under the supervision of a Certified Medical Physicist (CMP) specializing in the same sub-field or under the supervision of a qualified individual with a level of professional experience and expertise equivalent to that of a CMP.

**Part III Oral Examination (Medical Physics Specialty)**
Prerequisites – successfully passed Parts I and II

**Continuing Education**

To maintain an IMPCB certificate, a certified medical physicist must satisfy the continuing education requirements periodically as specified in the document accompanying the original certification.

This is a certification program similar to what the IFMBE/CED could try to develop as several certification/registration programs in clinical engineering are developed. This program is described in detail in Appendix F.
APPENDIX A

1989 "Mutual Recognition of Qualifications for Clinical Engineers"

This document was created by the work of the IFMBE Clinical Engineering Working Group (1979-1985) and the IFMBE Clinical Engineering Division (1985-1989)
1. Guideline for Certification/Registration of Clinical Engineers.

Historical Background

1.1 At the International Conference on Medical and Biological Engineering held in Jerusalem in 1979, the I.F.M.B.E. under its Charter for Working Group established a Working Group on Clinical Engineering. The first goal which had been approved by the Federation's Administrative Council, was the establishment of criteria for the mutual recognition of qualifications in the field of clinical engineering. The working group was elevated to a Division of the Federation at the Helsinki Conference in 1985. The Working Group and subsequently the Board of the Clinical Engineering Division have met regularly in various countries and formulated a number of objectives.

1.2 The steady growth in the number of people throughout the world engaged in clinical engineering confirms the necessity to define clearly on a national basis the type of qualifications which should be required of those wishing to practice in the field of clinical engineering. Certification should be based upon a peer review. The peer review process is taken to mean one in which the assessment of an individual is performed by colleagues of the highest professional attainment. This is already well recognized as an essential ingredient in the quality of professional certification/registration throughout the world and forms the basis of the present proposals. It is the belief of the Federation that qualifications (or experience) beyond those normally accepted for registration/certification as a professional engineer are a necessary requirement for those wishing to practice as clinical engineers. The Board of the Clinical Engineering Division is of the firm opinion that such additional qualifications should be subject to certification through a similar review process.
The I.F.M.B.E. sees the establishment of criteria for the mutual recognition of qualifications for clinical engineers as being necessary for the following reasons:

1.2.1. It will improve the standards of health care delivery throughout the world both in developed and developing countries by establishing common professional standards for clinical engineers and via them, to technical staff.

1.2.2. It will facilitate the mobility of personnel between and within countries affiliated to the I.F.M.B.E. (subject to national registration requirements which may impose additional limitations in individual cases). Europe 1992 is a real example of how such standards can be used in the near future.

1.2.3. It will provide a generally agreed reference which governmental and international agencies may use to provide guidelines for the provision of clinical engineering education, services and staffing.

1.2.4. It will improve collaboration between the National Affiliates of the I.F.M.B.E. by stimulating through the Clinical Engineering Division a continuing dialogue on all matters relating to the field of clinical engineering.

1.2.5. It will disseminate an understanding of the educational and training systems for clinical engineering available in various countries and hence foster their development.

1.3. The I.F.M.B.E. recognizes that in the field of clinical engineering there currently exist several levels of competence and ability. It is the intention of the Federation to provide guidance on the various levels which it recognizes. The Federation recognizes that some levels may not be appropriate for all countries and the responsibility of implementing the Guidelines contained in this document must rest with individual National Affiliate countries.
1.4 A most important step in the unification of clinical engineering activities within the Federation is the establishment of mutual recognition between member societies of the highest level of professional competence in clinical engineering. This concept will be fostered by the I.F.M.B.E.'s Clinical Engineering Division. It is clear that mutual recognition between countries does not necessarily imply reciprocity. This may be affected by existing national legislation.

1.5. In establishing this first level of Clinical Engineering, the I.F.M.B.E. recognizes that there will be others which are appropriate to countries both within and outside the Federation: Examples occur with technical staff who repair or inspect biomedical instrumentation.

2. Clinical Engineering - a Definition

2.1. Clinical Engineering is taken to mean the safe and effective management of technology and the application of medical and biological engineering within the clinical environment for the advancement of health care.

2.2. This application is undertaken by, or under the supervision of, Clinical Engineers who bring to health care facilities a level of education, experience and accomplishments which enable them to responsibly, effectively and safely manage and interface with medical devices, instruments and systems, and their use during patient care; and who can, because of this level of competence, responsibly and directly serve the patient in collaboration with other health care professions.

3. The role of the Clinical Engineer

3.1. The Clinical Engineer is involved at many levels in the safe, appropriate and economical use of technology within the health care system. Supported by appropriate clinical engineering technicians, the professional Clinical Engineer is responsible for areas extending from the design and maintenance of hardware and software to quality control and where this is appropriate, to the interpretation of signals derived from medical instrumentation. Some of the principal areas of responsibility can be outlined as follows; no particular priority order is implied.
3.2. The Provision of advice on available technology

The range of technological devices and systems currently available to improve health care delivery is vast, extending from the simplest aid designed for use by a disabled patient at home, through the variety of medical equipment found in most hospitals, to the complex diagnostic and therapeutic equipment found in specialist centres. With each passing year, technological advances in topics such as instrumentation, materials science, computing and nuclear engineering have a significant impact on what it is feasible to implement for the benefit of patients. The Clinical Engineer has a responsibility to advise on the applicability of the available technology in the hospital or clinic, either in direct response to the presentation of a clinical problem, or by taking the initiative to introduce new products and methods as appropriate.

3.3 The evaluation and purchase of equipment

Clinical Engineers are consulted in the evaluation, purchase and installation of medical devices and instrumentation in terms of:

- The initial evaluation of equipment, taking into account its cost-effectiveness in the light of its purchase price, installation cost and running cost (staff, consumable and maintenance).

- The suitability of the equipment to perform the desired task within the proposed environment.

- The reputation of the equipment and its manufacturer in terms of reliability and the back-up available.

- The acceptance testing of the equipment and its subsequent installation in a safe and correctly functioning condition.

3.4. Maintenance

The planned preventative maintenance of medical equipment is vital in order to ensure safety and efficacy. Planned obsolescence and replacement of older equipment ensures a continuity of service. There is also a real need to check on the most effective form of maintenance contract and the performance of the supplier's or third-party maintenance staff. Alternatively, the clinical engineering staff may offer
an in-house corrective maintenance service.

3.5. Hazard prevention and reporting

Clinical Engineers have a significant responsibility for obviating hazardous situations. This includes the selection of equipment which conforms to national and international safety standards and the taking of the appropriate action on the receipt of Hazard Notices pertaining to potentially defective equipment or techniques. These may be generated from International, Governmental or commercial agencies. The Clinical Engineer should also promptly inform such agencies of hazardous situations when hazards are encountered.

3.6. Clinical Measurement

An increased objectivity and the use of scientific investigations in health care have led to a proliferation of clinical measurement techniques. Many of the measurement devices require a controlled operation by engineering staff, and may also require the services of a Clinical Engineer to interpret the raw data into a relevant summary for clinical use.

3.7. General technical support and facilities

The Clinical Engineer can contribute to a higher quality of care by the provision of engineering competence in many day-to-day problems; the supervision of workshops constructing special purpose apparatus, the modification of existing facilities to meet new demands or the upgrade of performance, computer programming and interfacing are examples of such a contribution to the work of a clinical team.

3.8. Education and training

Clinical Engineering staff have a responsibility to educate not only the next generation of their own kind, but also their medical colleagues and to some extent the consumers of health care provision. More specifically, these tasks can be described as follows:

The provision of in-service training for engineering personnel who have completed an adequate formal training by the careful development of suitable training schemes covering a range of clinical experience and responsibilities.
Lectures/courses/workshops aimed at providing medical staff, from student to qualified practitioner, with a clear view of what technology can offer the patient. Advice to consumer representative groups on the availability of hardware, the effective use of resources and the significance of new developments.

3.9. Research and Development

The involvement of a Clinical Engineer with a proposed technological solution to a health care problem should begin at the definition of the problem. In the clinic, problem formulation may require extensive measurements and analysis followed by a survey of similar cases before the design stage can properly be commenced. After the design has been finalized, adequately controlled trials of the resulting system will be necessary and the introduction of a new system into common usage is vital for an effective carry-over to result of research into practice.

4. Qualifications and Requirements for Mutual recognition of Clinical Engineers

4.1

A. Successful completion of a basic education in engineering, applied science or medicine as would be necessary to meet that part of the requirements for Full Membership of the National Society. In addition, there must be at least three years of approved clinical engineering experience as judged by the National Society, or

B. Have, in addition to achieving the basic education described in (A) above, have undergone a period of higher education and/or training in biomedical education and have had not less than two years experience pertinent to clinical engineering.

4.2. Additional Requirements

National Certification Authorities in individual countries may, at their discretion, but within the guidelines of the Clinical Engineering Division, impose such other conditions as may be dictated by local national practices. Any additional local requirements would form part of a total package scheme of the National Society concerned. The actual certification procedure is carried out by each individual country.

4.3. Code of Professional Conduct
Every Certified Clinical Engineer shall always so order his/her conduct as to uphold the dignity and reputation of his/her profession and to safeguard the public interest in matters of safety and health. He/she shall exercise his/her professional skill and judgement to the best of his/her ability and discharge his/her professional responsibilities; the interests of the patient are paramount and the overriding consideration must always be that no harm or distress will ensue for the individual or his/her family and that the doctor/patient relationship will in no way be impaired.

5. Mechanisms of International Endorsement

5.1. Each National Affiliate of the I.F.M.B.E., if it so wishes, will act as the stimulus for the establishment of a National Certification Authority in its country or agree to make use of an existing Authority if this is appropriate.

5.2 The National Certification Authority in each country participating in the international endorsement scheme will recommend individual candidates who have successfully completed a certification scheme recognized by the I.F.M.B.E. Clinical Engineering Division. Endorsement of the program will be conferred by the Board of the Division on behalf of the Division.

5.3. The Board of the I.F.M.B.E.'s Clinical Engineering Division consists of members experienced in clinical engineering and most them are elected by the National Affiliates. The Board has a Scientific and Professional Committee. The latter will scrutinise the schemes for certification submitted to the Board and provide help and guidance to countries who express this need.

5.4 A fee for endorsement of both national certification schemes will be determined from time to time in order to cover the administrative expenses related to this process. The fees will be non-refundable, and agreed with the co-operating National Certification Authorities.

5.5. Each co-operating National Affiliate will be responsible for establishing its National Certification Authority or for making use of an established Authority if one exists in that country. It is possible that more than one Authority may be in existence. Each NCA will in turn be responsible for establishing and
conducting examinations for candidates and recommending action to the Clinical Engineering Division. The exact form of the certification procedure will be left in the hands of individual NCAs and may consist of a written examination and/or an oral examination and the views of independent engineering and clinical referees.

In the case of sufficiently experienced candidates, it may be possible to proceed directly to the examination. For candidates not already having an adequate experience, it will be necessary for them to embark upon an approved course of practical training conducted under the aegis of referees. In all cases candidates will be expected to have already achieved Full Member status of their National Affiliate.

The NCA must comprise professionals with a broad experience of contemporary clinical engineering practice and those who are professionally capable of understanding the requirements of such a practice. The scope and standard of the examination and the candidate review criteria must be such that successful candidates will perform well with the specialty.

5.6 Each NCA shall publish operational guidelines which can be submitted for agreement with the Clinical Engineering Division. Examples of possible forms of certification arrangements may be obtained from the Division's Secretariat.

5.7 The funding of each NCA will be its own responsibility, although each may seek support from the associated National Affiliate Society.

5.8 Each NCA will need to establish a secretariat to which applications for certification can be directed and which will be responsible for communicating with the Clinical Engineering Division's secretariat. The NCAs secretariat may be that of the national Affiliate or separate.

6. Code of Conduct

The I.F.M.B.E. Clinical Engineering Division expects that each National Affiliate will respect the I.F.M.B.E. Code of ethics for Clinical Engineers.

7. Renewal of Certification

The I.F.M.B.E.s Clinical Engineering Division Board is
concerned that its International Endorsement of an individual’s certification should not become dated. For this reason, it proposed that the Endorsement should be valid for an initial period of five years. It could be renewed for additional periods of five years on application by the relevant National Certification Authority.

This would prevent individuals to claim that they were Certificated Clinical Engineers even though they had ceased active practice in this field. NCAs might well also wish to limit the period of certification but making it renewable subject to satisfactory performance.

The NCAs are expected to keep public registers of their certified Clinical Engineers and to provide an update copy to the Clinical Engineering Division on a yearly basis.

Note: The provisions of International Certificates are a voluntary scheme and will be awarded, upon request, to countries whose schemes are submitted for approval and approved by the Clinical Engineering Division Board.
APPENDIX B

1989 “Mutual Recognition of Qualifications for Clinical Engineers”

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1.2.1. It will improve the standards of health care delivery throughout the world both in developed and developing countries by establishing common professional standards for clinical engineers and via them, to technical staff.

1.2.2. It will facilitate the mobility of personnel between and within countries affiliated to the I.F.M.B.E. (subject to national registration requirements which may impose additional limitations in individual cases). Europe 1992 is a real example of how such standards can be used in the near future.

1.2.3. It will provide a generally agreed reference which governmental and international agencies may use to provide guidelines for the provision of clinical engineering education, services and staffing.

1.2.4. It will improve collaboration between the National Affiliates of the I.F.M.B.E. by stimulating through the Clinical Engineering Division a continuing dialogue on all matters relating to the field of clinical engineering.

1.2.5. It will disseminate an understanding of the educational and training systems for clinical engineering available in various countries and hence foster their development.

1.3. The I.F.M.B.E. recognizes that in the field of clinical engineering there currently exist several levels of competence and ability. It is the intention of the Federation to provide guidance on the various levels which it recognizes. The Federation recognizes that some levels may not be appropriate for all countries and the responsibility of implementing the Guidelines contained in this document must rest with individual National Affiliate countries.
1.4 A most important step in the unification of clinical engineering activities within the Federation is the establishment of mutual recognition between member societies of the highest level of professional competence in clinical engineering. This concept will be fostered by the I.F.M.B.E.s Clinical Engineering Division. It is clear that mutual recognition between countries does not necessarily imply reciprocity. This may be affected by existing national legislation.

1.5. In establishing this first level of Clinical Engineering, the I.F.M.B.E. recognizes that there will be others which are appropriate to countries both within and outside the Federation: Examples occur with technical staff who repair or inspect biomedical instrumentation.

2. Clinical Engineering - a Definition

2.1. Clinical Engineering is taken to mean the safe and effective management of technology and the application of medical and biological engineering within the clinical environment for the advancement of health care.

2.2. This application is undertaken by, or under the supervision of, Clinical Engineers who bring to health care facilities a level of education, experience and accomplishments which enable them to responsibly, effectively and safely manage and interface with medical devices, instruments and systems, and their use during patient care; and who can, because of this level of competence, responsibly and directly serve the patient in collaboration with other health care professions.

3. The role of the Clinical Engineer

3.1. The Clinical Engineer is involved at many levels in the safe, appropriate and economical use of technology within the health care system. Supported by appropriate clinical engineering technicians, the professional Clinical Engineer is responsible for areas extending from the design and maintenance of hardware and software to quality control and where this is appropriate, to the interpretation of signals derived from medical instrumentation. Some of the principal areas of responsibility can be outlined as follows; no particular priority order is implied.
3.2. The Provision of advice on available technology

The range of technological devices and systems currently available to improve health care delivery is vast, extending from the simplest aid designed for use by a disabled patient at home, through the variety of medical equipment found in most hospitals, to the complex diagnostic and therapeutic equipment found in specialist centres. With each passing year, technological advances in topics such as instrumentation, materials science, computing and nuclear engineering have a significant impact on what it is feasible to implement for the benefit of patients. The Clinical Engineer has a responsibility to advise on the applicability of the available technology in the hospital or clinic, either in direct response to the presentation of a clinical problem, or by taking the initiative to introduce new products and methods as appropriate.

3.3 The evaluation and purchase of equipment

Clinical Engineers are consulted in the evaluation, purchase and installation of medical devices and instrumentation in terms of:

- The initial evaluation of equipment, taking into account its cost-effectiveness in the light of its purchase price, installation cost and running cost (staff, consumable and maintenance).

- The suitability of the equipment to perform the desired task within the proposed environment.

- The reputation of the equipment and its manufacturer in terms of reliability and the back-up available.

- The acceptance testing of the equipment and its subsequent installation in a safe and correctly functioning condition.

3.4. Maintenance

The planned preventative maintenance of medical equipment is vital in order to ensure safety and efficacy. Planned obsolescence and replacement of older equipment ensures a continuity of service. There is also a real need to check on the most effective form of maintenance contract and the performance of the supplier's or third-party maintenance staff. Alternatively, the clinical engineering staff may offer
an in-house corrective maintenance service.

3.5. Hazard prevention and reporting

Clinical Engineers have a significant responsibility for obviating hazardous situations. This includes the selection of equipment which conforms to national and international safety standards and the taking of the appropriate action on the receipt of Hazard Notices pertaining to potentially defective equipment or techniques. These may be generated from International, Governmental or commercial agencies. The Clinical Engineer should also promptly inform such agencies of hazardous situations when hazards are encountered.

3.6. Clinical Measurement

An increased objectivity and the use of scientific investigations in health care have led to a proliferation of clinical measurement techniques. Many of the measurement devices require a controlled operation by engineering staff, and may also require the services of a Clinical Engineer to interpret the raw data into a relevant summary for clinical use.

3.7. General technical support and facilities

The Clinical Engineer can contribute to a higher quality of care by the provision of engineering competence in many day-to-day problems; the supervision of workshops constructing special purpose apparatus, the modification of existing facilities to meet new demands or the upgrade of performance, computer programming and interfacing are examples of such a contribution to the work of a clinical team.

3.8. Education and training

Clinical Engineering staff have a responsibility to educate not only the next generation of their own kind, but also their medical colleagues and to some extent the consumers of health care provision. More specifically, these tasks can be described as follows:

The provision of in-service training for engineering personnel who have completed an adequate formal training by the careful development of suitable training schemes covering a range of clinical experience and responsibilities.
Lectures/courses/workshops aimed at providing medical staff, from student to qualified practitioner, with a clear view of what technology can offer the patient. Advice to consumer representative groups on the availability of hardware, the effective use of resources and the significance of new developments.

3.9. Research and Development

The involvement of a Clinical Engineer with a proposed technological solution to a health care problem should begin at the definition of the problem. In the clinic, problem formulation may require extensive measurements and analysis followed by a survey of similar cases before the design stage can properly be commenced. After the design has been finalized, adequately controlled trials of the resulting system will be necessary and the introduction of a new system into common usage is vital for an effective carry-over to result of research into practice.

4. Qualifications and Requirements for Mutual recognition of Clinical Engineers

4.1 A Successful completion of a basic education in engineering, applied science or medicine as would be necessary to meet that part of the requirements for Full Membership of the National Society. In addition, there must be at least three years of approved clinical engineering experience as judged by the National Society, or

B. Have, in addition to achieving the basic education described in (A) above, have undergone a period of higher education and/or training in biomedical education and have had not less than two years experience pertinent to clinical engineering.

4.2. Additional Requirements

National Certification Authorities in individual countries may, at their discretion, but within the guidelines of the Clinical Engineering Division, impose such other conditions as may be dictated by local national practices. Any additional local requirements would form part of a total package scheme of the National Society concerned. The actual certification procedure is carried out by each individual country.

4.3. Code of Professional Conduct
Every Certified Clinical Engineer shall always so order his/her conduct as to uphold the dignity and reputation of his/her profession and to safeguard the public interest in matters of safety and health. He/she shall exercise his/her professional skill and judgement to the best of his/her ability and discharge his/her professional responsibilities; the interests of the patient are paramount and the overriding consideration must always be that no harm or distress will ensue for the individual or his/her family and that the doctor/patient relationship will in no way be impaired.

5. Mechanisms of International Endorsement

5.1. Each National Affiliate of the I.F.M.B.E., if it so wishes, will act as the stimulus for the establishment of a National Certification Authority in its country or agree to make use of an existing Authority if this is appropriate.

5.2. The National Certification Authority in each country participating in the international endorsement scheme will recommend individual candidates who have successfully completed a certification scheme recognized by the I.F.M.B.E. Clinical Engineering Division. Endorsement of the program will be conferred by the Board of the Division on behalf of the Division.

5.3. The Board of the I.F.M.B.E.'s Clinical Engineering Division consists of members experienced in clinical engineering and most them are elected by the National Affiliates. The Board has a Scientific and Professional Committee. The latter will scrutinise the schemes for certification submitted to the Board and provide help and guidance to countries who express this need.

5.4. A fee for endorsement of both national certification schemes will be determined from time to time in order to cover the administrative expenses related to this process. The fees will be non-refundable, and agreed with the co-operating National Certification Authorities.

5.5. Each co-operating National Affiliate will be responsible for establishing its National Certification Authority or for making use of an established Authority if one exists in that country. It is possible that more than one Authority may be in existence. Each NCA will in turn be responsible for establishing and
conducting examinations for candidates and recommending action to the Clinical Engineering Division. The exact form of the certification procedure will be left in the hands of individual NCAs and may consist of a written examination and/or an oral examination and the views of independent engineering and clinical referees.

In the case of sufficiently experienced candidates, it may be possible to proceed directly to the examination. For candidates not already having an adequate experience, it will be necessary for them to embark upon an approved course of practical training conducted under the aegis of referees. In all cases candidates will be expected to have already achieved Full Member status of their National Affiliate.

The NCA must comprise professionals with a broad experience of contemporary clinical engineering practice and those who are professionally capable of understanding the requirements of such a practice. The scope and standard of the examination and the candidate review criteria must be such that successful candidates will perform well with the specialty.

5.6 Each NCA shall publish operational guidelines which can be submitted for agreement with the Clinical Engineering Division. Examples of possible forms of certification arrangements may be obtained from the Division's Secretariat.

5.7 The funding of each NCA will be its own responsibility, although each may seek support from the associated National Affiliate Society.

5.8 Each NCA will need to establish a secretariat to which applications for certification can be directed and which will be responsible for communicating with the Clinical Engineering Division's secretariat. The NCAs secretariat may be that of the national Affiliate or separate.

6. Code of Conduct

The I.F.M.B.E. Clinical Engineering Division expects that each National Affiliate will respect the I.F.M.B.E. Code of ethics for Clinical Engineers.

7. Renewal of Certification

The I.F.M.B.E.'s Clinical Engineering Division Board is
concerned that its International Endorsement of an individual's certification should not become dated. For this reason, it proposed that the Endorsement should be valid for an initial period of five years. It could be renewed for additional periods of five years on application by the relevant National Certification Authority.

This would prevent individuals to claim that they were Certificated Clinical Engineers even though they had ceased active practice in this field. NCAs might well also wish to limit the period of certification but making it renewable subject to satisfactory performance.

The NCAs are expected to keep public registers of their certified Clinical Engineers and to provide an update copy to the Clinical Engineering Division on a yearly basis.

Note: The provisions of International Certificates are a voluntary scheme and will be awarded, upon request, to countries whose schemes are submitted for approval and approved by the Clinical Engineering Division Board.

1989- Revised Version
APPENDIX

The IFMBE International Register of Clinical Engineers
INTERNATIONAL FEDERATION FOR
MEDICAL AND BIOLOGICAL ENGINEERING

THE IFMBe
INTERNATIONAL REGISTER OF CLINICAL ENGINEERS

Agreement on mutual recognition of qualifications for clinical engineers

BIOMEDEA
The IFMBE International Register of Clinical Engineers

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INTERNATIONAL FEDERATION OF MEDICAL & BIOLOGICAL ENGINEERING

AGREEMENT

on

Mutual Recognition of Qualifications

for Clinical Engineers

(Original Agreement: October 1981)
INTERNATIONAL REGISTRATION OF CLINICAL ENGINEERS

1. Historical Background

1.1 At the International Conference on Medical and Biological Engineering which was held in Jerusalem in 1979, the IFMBE under its Charter for Working Groups established a working group on Clinical Engineering. This working group has met on a number of occasions and formulated several goals. The first of these goals, which has been approved by the Administrative Council of IFMBE, is the establishment of criteria for the mutual recognition of qualifications in the field of clinical engineering.

1.2 The growth of the number of people throughout the world in the field of clinical engineering suggests that it is now appropriate to define clearly, preferably through peer review, the type of qualifications that should be required by those intending to practice in the field. The peer review process is taken to mean one in which assessment of an individual is carried out by colleagues of (usually) the highest professional attainment, and is already well recognised as an essential ingredient in the quality of professional registration throughout the world, and is the basis of the present proposals. It is the belief of the IFMBE that qualifications (or experience) beyond those normally agreed for registration as a professional engineer are a necessary requirement for those wishing to practice in the field of clinical engineering. We believe, furthermore, that such additional qualifications should he subject to certification through a similar review process.

The IFMBE sees the establishment of criteria for the mutual recognition of qualifications for those practicing in the field of clinical engineering as being necessary for the following reasons:

(i) it will improve the standards of healthcare delivery throughout the world both in developed and developing countries by establishing common professional standards of practice for clinical engineers and technicians;

(ii) it will facilitate a ready exchange of personnel between and within member countries of the IFMBE (subject only to such national registration that may impose additional limitations in individual cases – see Appendix 1);

(iii) it will provide an agreed reference which governmental and international agencies may use to provide guidelines for the provision of clinical engineering education, services and staffing;

(iv) it will improve collaboration between the member societies of the IFMBE by stimulating, through the Working Group on Clinical Engineering, a continuing dialogue on all matters relating to the field of clinical engineering;

(v) it will increase the understanding of education and training systems for clinical engineering in different countries and thereby foster their development.

1.3 The IFMBE recognises that in the field of clinical engineering there are several levels of competence and ability. It is the intention of the IFMBE to provide guidance on the various levels which it recognises, and to provide the seal of approval on those who reach various levels. The Federation recognises that some levels may be inappropriate for certain countries and the responsibility of this document rests with the National Societies as and when they see fit.
1.4 As a first step towards the unification of clinical engineering throughout the world the working group is proposing that a scheme of mutual recognition between member societies, of the highest level of competence, should be established as soon as possible. It should be noted that mutual recognition does not necessarily imply reciprocity, though this is clearly the long term aim of the IFMBE. (Reciprocity may be affected by existing national legislation).

1.5 In establishing this first level, the IFMBE recognises that there will be others which are appropriate to countries both within and outside the Federation: these will be the subject of further discussion and will be circulated both within and outside the IFNBE in due course.

2. Clinical Engineering: a definition

2.1 Clinical engineering is taken to mean the application of medical and biological engineering within the clinical environment, for the enhancement of health care.

2.2 Such application is undertaken by, or under the Supervision of, clinical engineers who bring to health care facilities a level of education, experience and accomplishments which enable them to responsibly, effectively and safely manage and interface with medical devices, instruments and systems, and the use thereof, during patient care; and who can, because of this level of competence, responsibly and directly serve the patient in collaboration with other health care professions.

3. Role of the Clinical Engineer

3.1 The clinical engineer is involved at many levels in the safe, appropriate and economical use of technology in the health care system. Supported by clinical engineering technicians, the professional engineer is responsible for areas extending from design and maintenance of hardware to quality control and, where appropriate, the interpretation of signals from medical instrumentation. Some of the principal areas of responsibility can be outlined as follows. No priority is implied.

3.2 An Advisory Service on Available Technology.
The range of technological devices and systems available to improve health care is vast, extending from the simplest aid intended for use by a disabled patient in a domiciliary setting, through the variety of medical equipment standard in many hospitals, to the most complex electronic diagnostic and therapeutic equipment available as yet to few With every passing year, technological advances in areas such as instrumentation, materials science, Computer manufacture and nuclear engineering have significant impact on what it is feasible to implement for the benefit of the patient. The clinical engineer has a responsibility to advise on the applicability of such technology in the clinic, either in direct response to the presentation of a clinical problem, or by taking the initiative to introduce new products and methods as appropriate.

3.3 Evaluation and Purchase.
Clinical Engineers should be consulted in the evaluating, purchase and installation of equipment as follows:
- evaluation of equipment, taking into account cost-effectiveness, running and manning costs and subsidiary expenses
- suitability of equipment to perform the desired task in the proposed environment
- safety of the equipment in the proposed environment
- purchase of the equipment, with respect to the required service and back-up from the manufacturer
- incoming inspection of new equipment, installation of the equipment in a safe and functioning condition.

3.4 Maintenance.
Planned maintenance of equipment is vital to ensure safety and efficiency, and planned obsolescence and replacement of older equipment ensures continuity of service. These are important areas for the clinical engineering staff to arrange and supervise.

3.5 Hazard prevention.
Clinical engineers are responsible for obviating hazardous situations. This includes taking appropriate action an the receipt of Hazard Notices pertaining to potentially defective equipment or techniques as received from International, National, Government or commercial agencies. The clinical engineer should also inform such agencies as appropriate of hazards or hazardous situations.

3.6 Clinical measurement.
Increased objectivity and scientific investigation in health care has led to a proliferation of clinical measurement techniques. Many of the measurement devices require controlled operation by engineering staff, and many require the service of a clinical engineer to interpret the raw data into a relevant summary for clinical use.

3.7 General technical support and facilities.
The clinical engineer can contribute to a higher quality of care by providing engineering competence in many day-to-day problems; supervision of workshops providing special purpose equipment, modification of existing facilities to meet new demands or upgrade performance, computer programming and extension of computer facilities, are examples of such a contribution.

3.8 Education and training.
The clinical engineering personnel have a responsibility to educate not only the next generation of their own kind, but also their medical colleagues and the consumers of health care to some extent. More specifically, these tasks can be described as follows:
- provision of in-job training for engineering personnel who have completed adequate formal education, by the careful development of training schemes with a range of clinical experience and responsibilities;
- instructional lectures/courses/workshops aimed at providing medical staff, from student to qualified practitioner, with the clearest view of what technology can offer the patient;
- where appropriate, advice to consumer representative groups on availability of hardware, effective use of resources and new developments.

3.9 Research and Development.
The involvement of a clinical engineer with a proposed technological solution to a health care problem should begin at the point of problem definition. In the clinic, problem formulation may require extensive measurements and analysis followed by a survey of similar cases before the design stage can properly be started. After design, adequately controlled trials of the resultant system will be necessary and introduction of the new system into common use is vital for effective carry-over of research into practice.
4. Qualifications and requirements for international registration

4.1 Education and experience
In order to obtain international registration as a Clinical Engineer a candidate must:

- Have successfully completed a basic education in engineering or applied sciences to a level comparable with the examples given in Appendix 1, and have had not less than 3 years of pertinent clinical engineering experience,

or

- have, in addition to achieving the basic education described in (1) above have undergone a period of higher education and/or training in biomedical engineering, examples of which are given in Appendix 1, and have had not less than 2 years' experience pertinent to clinical engineering.

4.2 Additional Requirements.
National Examining Authorities (NEA’s) may, at their discretion, but with the approval of the IRB, impose such other conditions as may be dictated by local national practices.

4.3 Professional conduct.
Every Clinical Engineer who is registered with the International Registration Board shall at all times so order his/her conduct as to uphold the dignity and reputation of his/her profession and to safeguard the public interest in matters of safety and health and otherwise. He/she shall exercise his/her professional skill and judgment to the best of his/her ability and discharge his/her professional responsibilities with integrity.

In discharging these professional responsibilities, the interests of the patient are paramount and the over-riding consideration must always be that no harm or distress will ensue for the individual or his or her family and that the doctor/patient relationship will be in no way impaired.

4.4 Honorary registration.
The IRB may, at their absolute discretion, confer Honorary Registration on persons who do not satisfy conditions specified in 4.1 above, but who in the opinion of the IRB have made or are making valuable contributions to the subject of clinical engineering.

5. Mechanisms of registration

5.1 Registration of Clinical Engineers is the responsibility of the International Registration Board (IRB). Each Affiliated National Society (ANS) will act as the stimulus for the establishment of the NEA in each country, and each will act as the channel of communication with the IRB. This does not necessarily imply that each Society will be the examining body.

5.2 The NEA in each country will recommend individual candidates to the IRB for registration as a clinical engineer. Registration will be conferred by the IRB.

5.3 The IRB will consist of the Chairman of the NEA from each of the National Societies party to this present agreement, plus representatives of independent international bodies and others as appropriate. The Working Group on Clinical Engineering, together with independent authorities, will comprise the Provisional Board. The prime task of the Provisional Board will be
to establish the Constitution and Bye-Laws of the IRB. Such Bye-Laws and Constitution shall be submitted to the IFMBE's Administrative Council for approval.

5.4 A fee for certification, which is non-refundable, will be recommended from time to time and is to cover the cost of processing applications. The fee will be payable to the NEA and half will be forwarded to the IRB to defray their expenses.

5.5 Each ANS will be responsible for establishing a National Examining Authority. Each NEA will be responsible for setting up and conducting examinations for candidates and recommending action to the IRB. The exact form of the examination procedure will be left to the individual NEA's, and may consist of a written examination, an oral examination and the view of independent referees. This examination process may comprise any or all of these elements, but in all instances must satisfy the requirements of the IRB. The NEA must comprise professionals with a broad background in the practice of clinical engineering and those who are professionally capable of understanding the requirements of such a practice. The examination and the candidate review criteria must be meaningful so that successful candidates will perform well within the specialty without preventing well qualified individuals from attaining certification.

5.6 Each NEA shall publish operational guidelines for the approval of the IRB. Guidance on these may be obtained from the IFMBE's Working Group on Clinical Engineering.

5.7 Funding of the activities of each NEA will be its own responsibility though each may seek the support of its affiliated National Society.

5.8 The Constitution and Bye-Laws of each NEA will be submitted to the IRB for its approval. Once approved the Chairman of the NEA will become a member of the IRB.

5.9 Each NEA will also need to establish a secretariat to which applications for registration can be directed, and which will subsequently be responsible for applying to the IRB for conferment of Registration. (This secretariat may be the Society's own existing secretary or secretariat.)

6. Code of Confidentiality

The IFMBE hopes that each member country will develop its own code of confidentiality relating to patient information and access to patient records.

7. Reference

8. Declaration of Intent
We, as Affiliated National Societies of the International Federation for Medical and Biological Engineering mutually agree to recognise any holder of the IFMBE's certificate of Registration as a Clinical Engineer, subject only to such additional criteria as may be specified by each National Society in addition to this document.

Signed:

Austria ...........................  Italy ..........................
Australia .......................... Japan ..........................
Belgium ............................ Mexico ........................
Canada ............................. Netherlands .................
Denmark ............................ Norway ........................
Finland ............................. Spain ........................
F.R.Germany ....................... South Africa ....................
France .............................. Sweden ........................
G.D.R ............................... United Kingdom ..............
Hungary ............................. U.S.A. .........................
Israel ............................... Yugoslavia ......................
APPENDIX 1

Examples of National education systems and national variations of requirements for professional qualifications.
**United Kingdom (Biological Engineering Society)**

<table>
<thead>
<tr>
<th>Education Level</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-schooling (non-obligatory)</td>
<td>1 yr.</td>
</tr>
<tr>
<td>Primary schooling (obligatory)</td>
<td>6 yrs.</td>
</tr>
<tr>
<td>Secondary schooling (obligatory)</td>
<td>4-8 yrs.</td>
</tr>
<tr>
<td>'0' levels or Certificate of Secondary education</td>
<td>16</td>
</tr>
<tr>
<td>(some leave education at this point)</td>
<td></td>
</tr>
<tr>
<td>'A' levels</td>
<td></td>
</tr>
<tr>
<td>University or Polytechnic education</td>
<td>18-19 (entry)</td>
</tr>
<tr>
<td>3 yrs. B.Sc.</td>
<td>21-22</td>
</tr>
<tr>
<td>1 - 2 yrs. M.Sc.</td>
<td>22-24</td>
</tr>
<tr>
<td>3 - 4 yrs. Ph.D.</td>
<td>24-26</td>
</tr>
<tr>
<td>Postgraduate training</td>
<td>4 yrs.</td>
</tr>
<tr>
<td>Responsible experience</td>
<td></td>
</tr>
<tr>
<td>2 yrs. Chartered Engineer</td>
<td>29-31</td>
</tr>
</tbody>
</table>

**IFMBE Registration requirements.**

B.Sc. + 3 years experience

or

M.Sc. or Ph.D. (in bioengineering) + 2 years experience

Note: The IFMBE's registration requirements will only partly satisfy the U.K. registration requirements.

For U.K. registration as a Chartered Engineer additional training in a recognised U.K. Training Centre for 2 years will be required, plus 2 years of responsible experience. Where experience is offered in lieu of training, 2 years of relevant experience will count as 1 year of training (i.e. B.Sc. + 8 years experience as a minimum).
APPENDIX D

DRAFT CODE OF CONDUCT FOR IFMBE CLINICAL ENGINEERS

AND

CANADIAN MEDICAL and BIOLOGICAL ENGINEERING SOCIETY CODE of ETHICS
Draft Code of Conduct for Clinical Engineers associated with the International Federation for Medical and Biological Engineering

I. The responsibility of IFMBE Clinical Engineers for the welfare, health and safety of the hospital community, including patients, in which they work shall at all times come before their responsibility to the profession, to sectional or private interests or to other engineers.

2. IFMBE Clinical Engineers shall act so as to uphold and enhance the honour, integrity and dignity of their profession.

3. IFMBE Clinical Engineers shall only perform work in their areas of competence.

4. IFMBE Clinical Engineers shall build their professional reputation on merit and shall not compete unfairly.

5. IFMBE Clinical Engineers shall apply their skill and knowledge in the interest of their employer or client for whom they shall act, in professional matters, as faithful agents or trustees.

6. IFMBE Clinical Engineers shall give evidence, express opinions or make statements in an objective and truthful manner and on the basis of an adequate knowledge.

7. IFMBE Clinical Engineers shall continue their professional development throughout their careers and shall actively assist and encourage engineers under their direction to advance their knowledge and experience.

8. IFMBE Clinical Engineers shall at all times respect the confidentiality of medical information concerning the condition of patients with whom they are working and respect doctor-patient relationships.
The Canadian Medical and Biological Engineering Society
Code of Ethics

The purpose of the CMBES Code of Ethics is to provide members with a guide of moral principles for conducting their profession.

CMBES members shall:

1. Hold paramount the safety, health and welfare of the patient, public and co-workers.

2. Manage public resources with prudence and responsibility.

3. Defend the public's right to privacy and confidentiality.

4. Act to advance and promote the theory and practice of engineering sciences and technology in medicine and biology.

5. Strive to avoid conflicts of interests, and disclose conflicts should they arise.

6. Recognize and respect the contribution of others in health care, and those in the non-technical fields of medicine and biology.

7. Represent self, title and role accurately.

8. Perform work only for which adequate knowledge, expertise and qualification by training is possessed.

9. Comply with all relevant provincial, national and international standards and regulations.

10. Continually develop professional knowledge and skills and seek certification when appropriate.

11. Conduct all aspects of work honourably, legally, and with kindness and respect of all colleagues and clients.

12. Demonstrate sincerity, fairness and integrity in all professional interactions.

13. Uphold the principles outlined in this code of ethics.
APPENDIX

Chapter Four

"Human Resources for medical devices, the role of biomedical engineers", WHO, 2017
4 Certification

4.1 Defining certification

Professional certification is the process of issuing a certificate formally attesting that the knowledge, know-how, skills and competences acquired by professionals have been assessed and validated by a competent body against predefined standards. Appropriate career paths and opportunities, including professional registration, certification or licensing, should be available to all health professionals for the benefit of public health and patient safety. This chapter describes the introductory information, history, current status and future prospects of professional certification, and gives a number of examples of different national, transnational and global models. Biomedicine and health-care challenges in the 21st century demand regulation of all health professions worldwide, so certification of professionals in the field of BME is among the global priorities.

One of the professional approval processes used in BME is certification; but this term is sometimes confused with related terms like registration, accreditation, credentialing and licensing. To clarify the definitions, similarities and differences between the terms within the professional context is outlined below.

Credentialing: An umbrella term used for different approval processes including accreditation, certification, licensing and registration. “Credential” is defined as an attestation of qualification, competence or authority of professionals issued to individuals by a third party with the authority to do so. Obtained professional credentials demonstrate proficiency in the field of interest and identify individuals as committed to their profession, and provide assessment and recognition of their background, experience and legitimacy to meet predetermined and standardized criteria.

Certification: This is generally a third-party attestation that specified requirements related to persons, products, processes or systems have been fulfilled. In order to apply professional standards, increase the level of practice and protect the public, a professional organization may establish a certification. Professional certification earned by an individual to perform a job or task is often simply called “certification”. In this context certification is the process of issuing a certificate – a statement or declaration such as a diploma, degree, title, clearance, etc. – formally attesting that knowledge, know-how, skills and competences acquired by an individual have been assessed and validated by a competent body against predefined standards. Professional certification may further require certain work experience in a related field before certification is awarded, either for a lifetime or as a time-limited recognition of an individual. Certifications are usually earned from professional associations, but also from universities and private certifiers for some specific certifications. Certifications are very common in the health-care sector and are often offered by particular specialisms. An example of such a certification process is a physician who receives certification by a professional specialism board in the practice of, for instance, radiology. The most general type of certification is profession-wide and is intended to be portable to all places a certified professional might
work. Certification is a voluntary process and it is based on the premise that there is a right to work. However, it is not a permission to work, but rather a statement of completion or qualification, with the purpose to educate and inform. Certification may be withdrawn at any time by the issuing organization, but this does not stop individuals from working. Licensing and certification are similar in that they both require the achievement of a certain professional level.

**Accreditation:** A third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. It is a formal process of quality assurance through which accredited status is granted, showing it has been approved by the relevant legislative or professional authorities by having met predetermined standards. Accreditation standards are usually regarded as optimal and achievable, and are designed to encourage continuous improvement efforts within accredited organizations. Accreditation is often a voluntary process in which organizations choose to participate, rather than a process required by laws and regulations. It is common in the health-care sector, and an accreditation decision about a specific health-care organization is usually made following a periodic on-site evaluation by a team of peer reviewers, typically conducted every few years. Although the terms “accreditation” and “certification” are used interchangeably, accreditation usually applies only to organizations, while certification may apply to individuals, as well as to organizations. When applied to individual practitioners, certification usually implies that the individual has received additional education and training, and demonstrated competence in a specialist area beyond the minimum requirements set for licensing. When applied to an organization, or part of an organization, such as a laboratory, certification usually implies that the organization has additional services, technology or capacity beyond those found in similar organizations.

**Licensing:** This is generally a mandatory approval process by which a governmental authority grants time-limited permission (licence) to individuals or organizations, after verifying that they met predetermined and standardized criteria, to perform an activity that is otherwise forbidden, considered hazardous or which requires a high level of expertise. Licensing presumes that engagement in the particular field is a privilege rather than a right, so the given privilege may be withdrawn at any time by the issuing authority. The purpose of licensing is to restrict entry and strictly control a profession or activity by ensuring that the licensee has met eligibility requirements and passed some form of assessment, usually at the state level and required by law. The licence may be renewed periodically through payment of a fee or proof of continuing professional development, by inspection, etc. Licensing is common in medicine, nursing, pharmacy, psychology, social work, engineering, etc., but hardly ever in BME. The main aim of licensing is to protect public health and ensure patient safety. Professional associations are often an important resource and support to those looking to obtain a special level of certification or licence.

**Registration:** This concerns insertion on an official register organized by a regulatory body, usually by recording or registering certificates. Registration implies standards for training, professional skills, behaviour, health etc., which registrants must meet in order to become registered and must
continue to meet in order to maintain their registration or licence. In most cases, the terms “licensing” and “registration” are also used interchangeably.\(^{(68,69,70)}\)

### 4.2 International certification of biomedical engineers

There is considerable variety in the ways that different nations manage the certification of BME and related disciplines, including clinical engineers, rehabilitation engineers and biomedical technicians.

The International Federation for Medical Electronics and Biological Engineering was founded in 1959 and eventually shortened its name to the International Federation for Medical and Biological Engineering (IFMBE). Two special divisions are currently part of the organizational structure: Clinical Engineering Division (CED), and Healthcare Technology Assessment Division (HTAD). Originally established as a working group in 1979, the CED attained official division status in 1985.

In 1981, the Agreement on Mutual Recognition of Qualifications for Clinical Engineers was signed by 22 affiliated national associations (ANS) of the IFMBE (Austria, Australia, Belgium, Canada, Denmark, Finland, Federal Republic of Germany, France, German Democratic Republic, Hungary, Israel, Italy, Japan, Mexico, Netherlands, Norway, Spain, South Africa, Sweden, United Kingdom, United States of America and Yugoslavia), mutually agreeing to recognize any holder of IFMBE’s Certificate of Registration as a Clinical Engineer, subject only to such additional criteria as might be specified by individual ANS.

Mechanisms of registration were developed and elaborated as follows. The International Registration Board (IRB) is responsible for the registration of clinical engineers. The IRB consists of the chair of the national examining authority (NEA) from each of the ANS party to the agreement, plus representatives of independent international bodies and others as appropriate. Each ANS establishes the NEA in its country, and acts as a communication channel with the IRB. Each NEA recommends individual candidates to the IRB for registration. The CED establishes the constitution and by-laws of the IRB to be approved by the IFMBE Administrative Council. A non-refundable fee for certification covers the cost of processing applications. Each NEA publishes operational guidelines, submits its constitution and by-laws to be approved by the IRB, takes care of funding, participates in IRB’s activities through its chair, organizes collection and processing of applications, sets up and conducts examinations for candidates, and recommends actions to the IRB. The exact form of the examination process (written, oral, view, etc.) is left to the individual NEA, but has to satisfy the requirements of the IRB, i.e. has to be meaningful so that successful candidates perform well within the specialism without preventing well qualified individuals from attaining certification.

In order to obtain international registration as a clinical engineer, the agreement defined that a candidate must have successfully completed a basic education in engineering or applied sciences to BSc level and to have more than three years’ relevant clinical engineering experience, or, in addition to achieving a BSc, to have a MSc or PhD and/or training in BME and to have more than two years’ relevant clinical engineering experience. NEAs may, at their discretion, but with the approval of the IRB, impose additional requirements as dictated by local national practices. Two years’ relevant experience
counts as one year of training, where experience is offered instead of training.

Formally, this agreement seems still to be in place, but since registration and/or certification have never been made mandatory by national legislation in most of the countries, the agreement has been neglected and the project of international registration and/or certification has actually never been accomplished to a full extent using defined mechanisms, as elaborated above. A possible initial attempt to resolve this appeared via the first issue of an international directory of clinical engineers in 1994, containing names of more than 1200 individuals from 62 countries, with the intention to improve recognition, communication and networking within the global clinical engineering community. (71)

Though neither the law nor employers usually require certificates in clinical engineering, there is a significant interest in and need for clinical engineering certification, as shown by the latest global CED survey among clinical engineering professionals and associations. Biomedicine and health-care challenges in the 21st century demand regulation of all health professions worldwide, thus an international umbrella programme for certification in clinical engineering is among the priorities of the global clinical engineering community. Currently an ongoing CED project on international clinical engineering certification is expected to help in finally achieving this goal.

4.3 Certification by region

4.3.1 Certification in Africa

South Africa has a voluntary registration programme of clinical engineers, clinical engineering technologists and clinical engineering technicians, which is based on experience and academic requirements. They also include medical equipment repair personnel. In Zimbabwe the Health Profession Act does not recognize biomedical equipment technicians and engineers under allied health professionals. However, there is a Chief Medical Engineer in the Ministry of Health. The technicians and engineers are in the process of forming a national association to advocate for legal recognition within the act. Once they are recognized, they will be able to participate in the annual review of human capacity needs for the health-care sector. The Zimbabwean situation is a good example of the situation in most sub-Saharan African countries, although at least 17 countries have a registered association.

4.3.2 Certification in the Americas

Canada

Canada uses the International Certification Commission for Clinical Engineering and Biomedical Technology (ICC) for certifying biomedical equipment technicians (BMETs) and they add the requirement that an individual must have a BSc in biomedical technology to take the exam. The exam is developed by the Canadian Board of Examiners under the ICC. Under the laws of the Canadian provinces and territories, the use of the title “engineer” in a job description requires that the incumbent be licensed as a professional engineer in that jurisdiction. Canada has always taken the position that to be eligible to seek certification in clinical engineering an applicant must first obtain a licence as a professional engineer. Once a person is licensed as a professional engineer and is working in the field of clinical engineering, then they can apply to the Canadian Board of Examiners for Clinical Engineering Certification.

By 1980, it was recognized that engineers working in clinical engineering required a distinct but unrecognized body of knowledge to perform their tasks.
competently. Since there was no licensing process in place specifically for clinical engineering, leaders in Canada decided to establish a certification process that would be administered by competent members of the profession. In order to begin such an effort, discussions were held with colleagues in the United States of America who had undertaken a similar approach under the leadership of AAMI. Canadians with established track records working in the profession were certified (on the grounds of experience), and established the first Canadian Board of Examiners for Clinical Engineering Certification. They developed a written and an oral exam. This process of certification continued for a number of years. However, the initial rush of applicants dwindled and it remained a voluntary activity with limited visibility in the health-care community.

Adding further credibility to the process, the US Board of Examiners is accountable to the Health Technology Certification Commission (HTCC), which oversees the work of the board and ultimately decides on recommendations from the board to certify individuals. Discussions between the Canadian and American boards gained support and encouragement from American colleagues. The main issue of divergence of practice between clinical engineers in the two countries relates to the country specific codes, regulations and standards, an important but relatively small part of the written exam. In discussion, it was agreed that members of the Canadian board would review the American written exam, to identify those questions requiring specific knowledge of American codes, standards and regulations. Canadian candidates are examined through a slightly different but parallel process to their American counterparts.(72)

It was agreed that Canadian applicants would register and be administered by the secretariat to the American board, to avoid setting up a parallel office in Canada. Sites are available in Canada to sit for the written exam, which is made available in both countries on a single date and time each year, early in November. All policies and procedures are harmonized and the Canadian board assists the American board in the generation of new written and oral exam questions. Members of the two boards discuss their work on a regular basis, and the chairs of each sit on the HTCC. The harmonized process was established in 2010 and remains in place. There has been good communication between the two boards, and a generally high level of support for the harmonized process.

**United States of America**

**Certified biomedical equipment technicians**

Certification in the United States of America in the clinical engineering field began with biomedical equipment technicians. A taskforce was established by the Association for the Advancement of Medical Instrumentation (AAMI) to look at the BMET field and the maintenance of medical equipment in hospitals. The taskforce decided that certification was needed to allow BMETs to demonstrate that they had a minimum level of expertise. A board of examiners was established by AAMI and the first exam set in 1970. Individuals who passed the written exam became certified biomedical equipment technicians (CBETs).

Specialist exams were also developed by AAMI for BMETs who work on laboratory and radiological equipment. These BMETs do not have to take the general exam since they only work on specialized equipment, but they need certification to demonstrate a minimum level of expertise in their specialism. Individuals who pass these exams become certified radiological equipment specialists (CRES) and clinical laboratory equipment specialists (CLES).
Certified clinical engineers

Individuals must meet the following qualifications to take the certified clinical engineer (CCE) exam: three years of clinical engineering experience plus a professional engineer licence or MSc in engineering or a BSc in engineering plus four years' total engineering experience, or BSc in engineering technology plus eight years' total engineering experience.

The written and oral exams are developed by the board of examiners and are based on the body of knowledge developed by the American College of Clinical Engineering (ACCE). (73)

Brazil

In the 1990s, nine Brazilian clinical engineers were certified by the ICC and the Brazilian Board of Examiners for Clinical Engineering Certification was created. However, a certification programme has not yet been developed. (74)

Mexico

In 1991, the first Mexican clinical engineer was certified by the ICC and in 1993 the CCE exam was given in Mexico and three more Mexican clinical engineers were certified. In 1994, the Mexican Board of Examiners was approved by the ICC which accepted the affiliation of the Mexican Certification Commission. The recently established Mexican College of Biomedical Engineers will certify biomedical engineers, BMETs and rehabilitation engineers. For further information see: http://www.cib.org.mx/servicios.html. (75)

4.3.3 Certification in Asia

Commission for the Advancement of Health-care Technology Management in Asia

The Commission for the Advancement of Health-care Technology Management (CAHTMA) was initiated in 2005 with the endorsement of the Asian Hospital Federation (AHF), which is an international NGO, supported by members from 14 countries in the Asia-Pacific region. CAHTMA is a member of the IFMBE. It was established to provide a platform for health-care professionals to discuss and exchange ideas on healthcare technologies and practices. Central to these objectives are the promotion of best technology management practices, the certification of clinical engineering practitioners and health-care professionals, and the dissemination of appropriate management tools through seminars and workshops.

CAHTMA has certified a few clinical practitioners. Technicians are certified as a level one clinical practitioner with a written exam and experience which is similar to the ICC BMET. Engineers are certified as level two clinical practitioners with a written exam and an oral exam and experience which is similar to the HTCC CCE. To encourage more engineers to become certified, CAHTMA is going to use the process of certifying individuals based on credentials similar to the initial programme in the United States of America.

CAHTMA is also the certifying faculty for BME technology programmes which are developing with the increased need for technologists to maintain medical equipment. In 2012, lecturers at one school were tested as assessors and certified by CATHMA with the Certification for Clinical Engineering Assessors. Lecturers who completed five weeks of training and passed the exams were certified by CATHMA with the Certification for Clinical Engineering Trainers. (76)

China

In 2005, international clinical engineer certification was introduced in China. The Medical Engineering Division of the Chinese Medical Association hosted the first international clinical engineering certification training courses and
certification examination. The written exam is based on the ACCE body of knowledge with some adjustment for the practice of clinical engineering in China. The written exam is in English and is prepared by international senior specialists. Individuals who pass this 100-question multiple choice exam have to then pass an oral exam in English to become certified. The oral exam is given by the international senior specialists. In the seven training sessions since 2005, 760 clinical engineering personnel have attended. Some 252 individuals have passed the two exams and been certified as international clinical engineers. The candidates for certification are mostly senior clinical engineers with more than 10 years’ experience. In 2012, the Medical Engineering Division of the Chinese Medical Association carried out Chinese Registered Clinical Engineer Certification (RCEC) training and examination. The candidates were junior engineers in large hospitals or new graduates with majors in medical engineering. This exam is the basic admission exam to the occupational qualification of clinical engineering. The RCEC exam consists of a theoretical exam and practical test. There is a Chinese exam question bank from which the theoretical questions are randomly selected. Candidates then take a practical test including repair, measurement and maintenance of medical devices. A committee of Chinese clinical engineering experts evaluates the ability of the candidates and determines if they are qualified to receive the Registered Clinical Engineer Certification.

China is establishing continuing education for both certifications to maintain and improve the quality of the clinical engineers. The Medical Engineering Division plans to recommend to the government to officially authorize clinical engineer training and certification. (77) In Hong Kong (SAR), China, BMETs take the ICC exam used in the United States of America; no Hong Kong board of examiners has been appointed. For CCE they use the American exam process under the HTCC. (78)

The Taiwan Society for Biomedical Engineering (TSBME) performs certification in clinical engineering in Taiwan, China. In 2000, TSBME established the Certification Executive Committee for Clinical Engineering certification. The first testing for certification of clinical engineers and technologists of medical equipment was in 2007. The TSBME provides certification for clinical engineers, medical equipment technicians and biomedical engineers. In 2010 they had certified 93 clinical engineers, 132 medical equipment technicians and 224 biomedical engineers. Clinical engineers and medical equipment technicians work in hospitals and biomedical engineers work in the medical device industry. This is the only certification that has a separate certification programme for hospital and industry engineers. (79)

Japan
In Japan the government certifies clinical engineering technologists (CET), who must graduate from a clinical engineering training school which can be a university, junior college or training school and pass a national exam to be certified. CETs are also called clinical engineers and are paramedics who specialize in the medical equipment essentials in medical care. About 35% work in haemodialysis and about 20% in maintenance. Others work in respiratory care, operating rooms, intensive care units, heart related, hyperbaric and other areas. In 1987 the clinical engineering system was established by the Clinical Engineers Act. This act created the CET as a professional medical position responsible for the operation and maintenance of life-support systems under the direction of doctors. This act established a national
qualification including a 180-question exam in medicine, engineering and medical technology. In 2010 there were about 28,000 certified CETs and about 18,000 currently working in the field. The certification of CETs is most equivalent to the CBET in the ICC system in the United States of America.\(^{(80,81)}\)

In addition to the CET certification by the government, the Japan Society for Medical and Biological Engineering has a BME certificate programme, which has two classes of certification for biomedical engineers. The first is for experienced clinical engineers and in 2008 the pass rate was 22.2% for 433 applicants. This exam covers basic aspects of medical engineering and medical device related subjects. The second exam is for students or recent graduates of clinical engineering and many take it as preparation for the national CET exam. In 2008 the pass rate for this exam was 29.3% for 1398 applicants.\(^{(82)}\)

### 4.3.4 Certification in Europe

In the European Union BME is not a regulated profession; hence there is no centralized, common certification programme that establishes certification standards for all European Union Member States. Further research will be needed to develop a strategy for official acknowledgement and certification for biomedical engineers in this region.

**Czech Republic**

Since 2004, the Act on Nonmedical Health Service Occupations and related regulations has recognized health service professionals with technical competences (biomedical technicians with a BSc in biomedical technology and biomedical engineers with a MSc in biomedical engineering) and health service specialists with specialized technical competences (clinical technicians with BSc in clinical technology and clinical engineers with a MSc in clinical engineering), in addition to similar legislation that had existed for decades for medical professionals. If workers with technical competences come into contact with patients or if they can directly impact patient health through their professional activities, they are required to have the qualification of either health service professional or health service specialist. There is an established system of both undergraduate and postgraduate, specialized and life-long education, accredited by ministries of education and health, to gain qualifications and appropriate certifications.

The graduates of accredited study programmes and fields get a certificate of qualification to perform health service occupations. Graduates of other BSc or MSc study programmes in electrical engineering can obtain a qualification for health service workers with technical competence if they complete the course in BME (MSc in engineering) or biomedical technology (BSc) accredited by the Ministry of Health. Graduates of other study programmes must complete specialized postgraduate courses in BME. The specialized technical competences for clinical technicians and clinical engineers can be obtained by completing specialized education and training provided by institutions accredited by the Ministry of Health, and by passing an official examination in front of the board appointed by the Ministry of Health. Clinical engineering as specialized education and training for biomedical engineers, and clinical technology for biomedical technicians are types of education organized by the Institute for Postgraduate Education in Health directly controlled by the Ministry of Health.

The Ministry of Health issues the official certificates for biomedical technicians/
engineers and clinical technicians/engineers. Then they can apply for registration in the Registry of Health Care Professionals, which is a part of the National Health Care Information System. They receive a certificate that is valid for six years and renewable thereafter under defined criteria. (83)

**Germany**

Germany has developed a certified clinical engineering programme, but it does not require an exam. It is based on experience and academic background. They are also planning to develop a certified BMET programme. In most European countries, there are more engineers than technicians and so the certification of the engineer is more important.

**Ireland**

In 2003, in anticipation of forthcoming legislation for Statutory Registration of Health and Social Care Professions, the Biomedical Engineering Association of Ireland and Biomedical Engineering Division of Engineers Ireland established the Clinical Engineering Voluntary Registration Board and an associated clinical engineering registration scheme, as a voluntary professional registration plan. The Clinical Engineering Voluntary Registration Board was composed of engineers from academia, practitioners from the public and private sector, and representatives of publically and privately funded hospitals. The plan considered education, clinical engineering experience, ethics, professional standing and continuing professional development (CPD).

The plan is based on achieving Engineers Ireland’s professional titles (engineering technician, associate engineer and chartered engineer). Engineers Ireland has statutory responsibility for the title of “chartered engineer” in Ireland. The three protected titles of Engineers Ireland require the achievement of a specified academic standard, a specified minimum number of years of experience, an interview based on a set of published competencies, and an engagement with a code of ethics. Engineers Ireland also has a well-developed plan to support “grandfathering” with a process which recognizes experience in lieu of academic qualifications by assessing candidates’ ability with respect to specific competencies. In addition, the plan includes an application form where two recognized practitioners sign-off on the candidates’ experience in the clinical engineering field. A voluntary CPD scheme was also developed. Since clinical engineering is a small profession in Ireland, statutory registration will not be implemented for some years. It is thought the Clinical Engineering Voluntary Registration Board plan will meet the short-term requirements for a registration plan. (84)

**Italy**

In Italy, a process of defining common rules for recognizing the activities of biomedical and clinical engineers and for the certification of the skills of engineers is currently in progress. The Territorial Associations of Professional Engineers have the right to set up voluntary certification of skills for their members. Recent Italian laws have explicitly mentioned clinical engineers and clinical engineering services, making the need for a certification procedure more pressing. The laws state that the Territorial Associations of Professional Engineers are responsible for defining a set of rules for certification. The document, being drafted by local BME committees, will identify a metric of evaluation that is based on the verification of the contents of the documents submitted for the recognition of skills, on the interview with the candidate and on the evidence for continuity of professional activity. (85)
Poland
In 2002 the programme of specialization in medical engineering for engineers as professionals in clinical environments was introduced by national legislation, under the auspices of the Ministry of Health, the Medical Centre of Postgraduate Education and the national consultant in the field of medical engineering, in a way similar to education and training programmes for medical professionals. The candidates for this specialization must have a MSc in BME, automatics and robotics, electronics and telecommunications, mechanical engineering or computer science, and at least three years’ work experience in a clinical environment. The workload of this postgraduate medical engineering specialization programme is 1700 hours over two to three years, with about half filled with lectures and laboratory exercises, and the rest placement in hospitals and clinics with appropriate facilities, equipment and staff for such activity, and being accredited by the State Commission for Accreditation.

At the end of the programme, in order to obtain the title and the certification as a specialist in medical engineering, the candidate has to pass the practical and theoretical parts of the state exam in front of the State Examination Commission. Professional competences gained during postgraduate education, entitles successful individuals to work in clinical environments as a medical engineer. Moreover, a participation of certified specialists in medical engineering in some advanced medical procedures is also required by law, as well as in the positions of national and regional consultants for medical engineering issues. (86)

Sweden
The Swedish Society for Medical Engineering and Physics started the Certification of Clinical Engineers in 1994. The certification is performed by an examination at two levels, corresponding approximately to BSc and MSc degrees in engineering, respectively. The BSc in engineering, as the lower level of certification, was chosen because in 1989 a Swedish law came into force, stating that a worker should preferably have at least this level of education to work in clinical engineering. At the time, there were many engineers working in clinical engineering departments in hospitals who did not possess a BSc but rather an older degree from a polytechnic institute. These engineers were accepted for certification if their degree dated 1989 or earlier, but they had to have at least six years’ instead of three years’ work experience.

Applications for certification are sent to the society twice a year, and are reviewed and judged by a certification committee with the mandate from the society's board. The certification committee consists of a chair (preferably a lawyer from a state health-care organization or a health-care provider), two university professors in BME, and two experienced certified clinical engineers.

The requirements, besides the engineering degree and minimum three years’ hospital work experience as a clinical engineer supervised by an experienced and preferably certified clinical engineer, are university/institution/company courses in biomedical or clinical engineering, medicine or related fields corresponding to at least 30 ECTS points assigned and collected under defined criteria. Since 1994, there have been a total of 695 applications, 571 at BSc level and 124 at MSc. Some 391 have been certified (304 BSc and 87 MSc).

A programme that certifies specialists in clinical engineering was developed in 2014. To become a certified specialist in
clinical engineering, the engineer should have at least two years’ specialist training supervised by an experienced and certified specialist in clinical engineering. The specialist training programme consists of courses corresponding to CPD, which are classified by the certification committee. Specialist training years should equal a minimum of 30 ECTS points. Certification of specialists is also performed at both BSc and MSc level in engineering. To keep specialist certification, clinical engineers should continue with their professional development through ongoing training and education. Different specialist programmes are currently under development: medical imaging, dialysis, intensive care, computers in health care, responsibility and management, etc. (87)

**United Kingdom**
The United Kingdom initially developed a certification for clinical engineers in the 1990s but this programme has been dropped due to lack of interest. Currently there is voluntary registration for clinical scientists and clinical technologists, which includes professionals working in the field of clinical engineering and medical physics.
APPENDIX F

INTERNATIONAL MEDICAL PHYSICS CERTIFICATION BOARD (IMPCB)
Medical Physics Certification Process – Requirements
INTERNATIONAL MEDICAL PHYSICS CERTIFICATION BOARD (IMPCB)
Medical Physics Certification Process – Requirements

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INTRODUCTION

Background:

IMPCB is developing a program that allows:

I. Accreditation of National or Regional Boards that provide certification of Medical Physicists in their jurisdiction

II. Certification of individuals in countries where no National Boards exist.

In the first instance the documentation pertains to the first objective above even though it is recognised that the processes are informed also by the second objective.

In the process of developing the required procedures and guidelines, IMPCB has developed a Model Program (http://www.impcbdb.org/model-program/) to guide the initial set-up of the examination program. The present document is informed by this model. It is acknowledged, that this is by no means the only model that will be acceptable when evaluating certification Boards for accreditation. The IMPCB recognizes that there are national/regional variations to certification in medical physics based on differences in national/regional legislation and educational traditions. Consequently, IMPCB will give to national and regional certification bodies considerable freedom to decide on the manner in which a given organization seeking IMPCB accreditation conducts the certification process. The present document lays out requirements that IMPCB is considering using for its own examinations and which other certification Boards might like to use.

IMPCB is committed to work on other model programs in the future and/or provide links to other established Boards that use different models.

Accreditation of National or Regional Organisations or certification of individuals will be provided to several specialties of medical physics such as Radiation Oncology Physics; Diagnostic and Interventional Radiological Physics; Nuclear Medicine Physics; Non-ionizing Radiation Physics; Medical Health Physics and Physiological Measurement. Given the current demands and workforce requirements the first three specialties to be considered are Radiation Oncology Physics, Diagnostic and Interventional Radiological Physics and Nuclear Medicine Physics.

Accreditation or certification procedures and the examination of medical physicists through IMPCB consist in general of three parts:

a. Part I is designed to accredit or certify in fundamental aspects of medical physics (General Medical Physics).

b. Part II is designed to accredit or certify in a specialty area of medical physics, (such as Radiation Oncology Physics; Diagnostic and Interventional Radiological Physics; Nuclear Medicine Physics; Non-ionizing Radiation Physics; Medical Health Physics; Physiological Measurements)

c. Part III is designed to accredit or certify fitness to practice clinical medical physics in a designated specialty, (such as Radiation Oncology Physics; Diagnostic and Interventional Radiological Physics; Nuclear Medicine Physics; Non-ionizing Radiation Physics; Medical Health Physics; Physiological Measurement).

d. Parts I and II are assessed in a written examination process while Part III should be conducted as an oral examination. Candidates are expected to pass both Part I and Part II before taking Part III.

It is anticipated that candidates progress through the three parts in sequence. Persons who may qualify only for Part I or Parts I and II may undergo these examinations only. IMPCB can provide a certificate record to candidates who have only passed either Part I or Part I and II on request.
**Purpose of the present document**

The present document details requirements for certification of individuals and provides one possible model for certification boards established by National or Regional Organisations that apply for accreditation. It is structured into three separate parts pertaining to the three parts of the examination detailed above. The criteria were developed by the Accreditation Committee (AC) of IMPCB through three subcommittees which were dealing with the three parts of the examination. An attempt was made to 'harmonise' the documentation for the three parts. However, given the difference in scope, the difference in examination approach and the differences of other existing relevant documents for the three parts some differences remain.

The IMPCB recognizes that there are national/regional variations to certification in medical physics based on differences in national/legislation and educational traditions, so it gives national and regional certification bodies considerable freedom to decide on the manner in which a given organization seeking IMPCB accreditation conducts the certification process. Thus, IMPCB describes the examination process only in general terms; however, the certification body, in order to gain and maintain IMPCB accreditation, must comply with the examination process for which it obtained accreditation. In assessing an application for accreditation IMPCB will take into consideration IOMP Policy Statements 1 and 2 as well as the local circumstances of the respective certification board. Individuals will be certified after fulfilling the requirements set out in the present document.

Several important issues are not covered in the present document. They pertain to:

- Requirements for Continuing Professional Development (CPD) and 'Re-certification Requirements
- Consideration of interim or temporary certification
- Consideration of languages other than English
- Provisions for 'grandfathering in' medical physicists who have appropriate credentials
- Guidelines for training and education programmes

**Structure of the document**

The document is divided into three main parts detailing the requirements for the three parts of the examination process.

Parts I and II are similar in their format and consist of three sections: General considerations and format; Process of examination; and, Subjects covered. The latter is typically listed for the three specialties and divided into ‘knowledge’ and ‘skills’ sections. Part III requires a slightly different structure.

The document concludes with a bibliography and some examples for questions in an appendix. For additional examples please also refer to [http://www.theabr.org/ic-rp-sample](http://www.theabr.org/ic-rp-sample).
PART I:  
Requirements for successful completion of Part I of the exam

The following requirements list both undergraduate and postgraduate requirements for candidates who wish to be examined for Part I of the IMPCB certification. The weighting of the different components may vary from country to country depending on the general physics education and other local considerations. It is assumed that the examination will be conducted in a written format. Commensurate with the nature of the contents of Part I, the requirements distinguish between required knowledge and skills which are detailed in the following sections.

A. General considerations and format

The Part I written examination will be based on questions presented in one or more of the following formats:

i. Multiple choice (MC).
ii. Short answer.
iii. Essay type.
iv. Computational type.
v. Random choice from a large question bank available to candidates ahead of the examination. The examination committee determines the random choice of a predetermined number of questions from the examination booklet.

Multiple choice questions are deemed an appropriate approach to written examinations since they offer reliability, result in objective testing of a candidate's knowledge and skills, are cost-effective, and provide a record of a candidate's performance. They are easy to use in an examination setting; however, they are also time consuming and difficult to compose in an unambiguous form. MC questions typically fall into one of the following three MC question types: (a) Traditional MC questions, (b) Multiple True – False MC questions, and (c) Matching MC questions.

MC-based examinations also suffer several disadvantages in contrast to standard written and oral examinations, such as: (a) They contain the correct answer to each question allowing for the choice of the correct answer instead of asking for the formulation of the correct answer, (b) It is possible to stumble upon the correct answer to a MC question through guesswork, (c) They are purely binary and no partial marks are possible. Additional comments on multiple choice questions are provided in appendix 1.

Short answer and essay type (long answer) questions can be defined well and allow the candidate to explain succinctly the salient features of the correct answer. These questions are most suitable for candidates with average or superficial knowledge of the subject, but present problems for candidates with either no knowledge of the subject (zero marks) or extensive knowledge of the subject (full marks but exam time can be lost by delving too deep into the question). Partial marks are possible.

A computational question expects the candidate to calculate the final numerical answer to a specific problem through formulating the general solution based on physical principles involved in the question. Partial marks are possible.

Random choice from a question bank is based on an examination booklet available to candidates prior to the examination. This examination format has been used successfully by the Canadian College of Physicist in Medicine (CCPM) for the past 30 years and the CCPM examination committee updates the booklet every few years. The booklet is quite extensive, covers all the important specialties of medical physics, and serves as an excellent syllabus.
for candidates preparing for their specific specialty examination. The questions can be quite elaborate and consist of several sub-questions covering a specific subject with a mixture of many formats such as short and long essays, drawing of schematic diagrams as well as computational problems. Partial marks are possible.

B. Process of examination

The IMPCB recommends that Part I certification examination consist of several components each component containing questions presented in one or more of the formats given above.

National or regional bodies seeking IMPCB accreditation would be expected to decide on the format used for their certification examination and present their proposed examination format to the IMPCB for evaluation. Upon receiving an IMPCB accreditation, the certification body would be obliged to make examination candidates fully aware of the examination format and rules governing marking of the examination papers. The IMPCB recommends that Part I of the IMPCB-accredited certification examination contain several sections, with each section containing questions presented in one or more of the formats listed above.

Typical duration of the Part I IMPCB-accredited written examination will be 3 – 4 hours. Settings.

C. Subjects covered in the Part I examination shall be as follows

The subjects are distinguished between undergraduate subjects that would generally be expected as entry requirements into a medical physics program and postgraduate subjects that are specific to a medical physics course. The examination focuses on the postgraduate aspects only.

C1. Undergraduate Pre-requisites

Applicants are expected to have taken the following undergraduate courses to the level necessary for following a postgraduate Masters programme in Medical Physics:

1. Physics
   - Classical and Relativistic Mechanics
   - Electricity and Magnetism
   - Optics
   - Physics of Fluids and Gases
   - Quantum Mechanics
   - Atomic and Nuclear Physics
   - Solid State Physics
   - Thermodynamics and Statistical Physics
   - Measurement, Instrumentation and Signal Processing
   - Computational Physics and Computer Programming

2. Mathematics
   - Applied Linear Algebra
   - Advanced Calculus
   - Complex Variables
   - Differential Equations
   - Numerical methods

Ref: IAEA (2013) TCS56 Postgraduate Medical Physics Academic Programmes
C.2. Biophysics and Basic Biomedical Sciences for Medical Physicists

Knowledge
1. Explain the basic biophysics (e.g., diffusion, osmosis, hemodynamics, biopotentials) and biochemistry necessary for an understanding of human anatomy and physiology.
2. Describe and explain cell structure, function, division and differentiation.
3. Describe using a systems approach the major systems of the human organism and the anatomy and physiology of component organs.
4. Explain the basis of human health, aetiology of disease (in particular carcinogenesis and heritable processes) and trauma.
5. Understand medical terminology and anatomical positions
6. Describe human development, growth and ageing
7. Describe normal anatomy /physiology and trauma / pathology in medical images

Skills
1. Recognize body organs and basic pathologies in medical images.

C.3. Clinical Medical Devices & Protection from Physical Agents

Knowledge
1. Overview of the following areas of physics applied in medicine:
   a. Properties, measurement, instrumentation and interaction with matter of ionizing and non-ionizing radiations,
   b. The principles of ionizing radiation dosimetry
2. Understand relevant international, regional and national legislation, standards and documentation regarding medical devices and risk from associated physical agents (with particular emphasis on radiological devices and ionizing radiation).
3. Describe the principles of protection from physical agents, with emphasis on ionizing radiation, with respect to patient, occupational and public risks.
4. Explain how to protect oneself from physical agents (particularly ionizing radiation)
5. Present an overview of the range of medical devices used in contemporary healthcare including: overview of commonly used medical devices, overview of the various imaging modalities, physiological measurement devices, therapeutic devices.
6. Utilize medical device and DICOM standard terminology.
7. Explain the principles of medical device management including planning, evaluation of clinical needs, preparation of technical specifications for tender purposes, evaluation of tendered devices, procurement, acceptance testing, commissioning, constancy testing, maintenance, decommissioning and service contract management.
8. Explain the principles of service quality development as applied to the use of medical devices and protection from physical agents.
9. Explain the effects of physical agents on the workings of medical devices (e.g. electromagnetic compatibility).
10. Describe procedures for the handling of adverse incidents related to medical devices and physical agents.

Skills
1. Demonstrate basic skill in the use of image processing software (e.g., Basic features of ImageJ).

Notes:
1. The material in this section of the syllabus is meant to lay a generic foundation for a more in-depth application specific to the specialty of Medical Physics chosen by the candidate in Part 2.
The level for ionising radiation physics and dosimetry required is for example that in the first 4 chapters of EB Podgorsak et al. Radiation Oncology Physics: A handbook for teachers and students. IAEA Vienna 2005.

In the case of students with a first degree in Engineering there may be the need to provide for lack of sufficient previous knowledge in quantum mechanics and atomic and nuclear physics.

C.4. Ionizing Radiation Physics and Dosimetry

The topics in this section of the syllabus are an elaboration of what is expected in Section C.3. (1) in the case of ionising radiation:

- Basic Radiation Physics
- Electron interactions
- Photon interactions
- Dosimetric principles
- Cavity theory
- Ionization chamber dosimetry
- Film dosimetry
- Luminescence dosimetry
- Semiconductor dosimetry
- Other dosimetry systems
- Primary standards
- Radiation monitoring instruments
- Operation quantities for radiation monitoring
- Area survey instrumentation
- Individual monitoring instrumentation

The level for ionising radiation physics and dosimetry required is for example that in the first 4 chapters of EB Podgorsak et al. Radiation Oncology Physics: A handbook for teachers and students. IAEA Vienna 2005.

C.5. Research Methods and Statistics for the Physical and Health Sciences and Medical Informatics

Knowledge
1. Review a particular area of research interest in own specialty of medical physics including associated professional, ethical, legal and educational issues.
2. Identify research objectives worthy of study.
3. Apply the main research designs used by physicists involved in biomedical and health sciences research.
4. Appreciate the strengths and limitations of each research design and select a particular research design for a given study.
5. Appreciate the importance of both qualitative and quantitative data in biomedical and health sciences research.
6. Discuss the following topics in Medical Informatics:
   - The Organization of Medicine
   - The Organization of Health Information
   - The Paper-based and Electronic Medical Record
   - Hospital Information Systems
   - Radiology Information Systems
Systems in Public Health:
- Disease Surveillance
- Chronic Disease Management
- Disease Registries
- Epidemiology
- Health Indicators
- Statistical reporting

eHealth
Information for the Healthcare Professional and Patient.

Issues in Telemedicine:
- Systems for Clinical Decision Making
- Artificial Intelligence in Medicine
- Expert Systems in Medicine
- Bioinformatics and the Genome Project

Measuring Quality and Outcomes
- Standards
- Quality Improvement

The Personal Health Record

Ethical and political issues

Skills
1. Demonstrate use of statistical methods for the analysis of physical, biomedical and health science data.

C.6. Principles of Biomedical Signal Processing for Medical Physics

Knowledge
1. Understand the origin and nature of biomedical signals.
2. Understand and apply the following signal processing principles to biomedical signals:
   a. Signal sampling and quantisation
   b. LTI systems
   c. Frequency domain analysis of signals
   d. Signal filtering
3. Use of appropriate signal processing software

Skills
1. Demonstrate use of basic signal processing software.
2. Demonstrate basic use of MATLAB for signal processing.

Note: There may be the need to provide for lack of sufficient previous knowledge in signal processing and use of Matlab.

C.7. Principles of Biomedical Image Processing for Medical Physics

Knowledge
1. Understand the origin and nature of biomedical images.
2. Understand and apply the following image processing principles to biomedical images:
   a. Generation of digital images,
   b. Intensity transformation in digital images,
   c. Spatial filtering,
d. Frequency domain filtering of images,
e. Image segmentation,
f. Classification of objects of interest in images,
g. Review of image compression techniques,

3. Use appropriate image processing software.

Skills
1. Demonstrate advanced skill in the use of image processing software (e.g., more advanced features of ImageJ).
2. Demonstrate basic use of MATLAB for image processing.
PART II
Requirements for successful completion of Part II of the exam

The following details the postgraduate requirements for candidates who wish to be examined for Part II of the IMPCB certification.

Part II of the IMPCB-accredited certification examination, similarly to Part I, will be given in the format of a written examination. In contrast to Part I that covers the basic aspects of medical physics with which all medical physicists should be familiar regardless of their chosen specialty, Part II concentrates on the candidate’s specialty. Currently IMPCB is focusing only on requirements for Radiation Oncology Medical Physics, Diagnostic and Interventional Radiological Physics and Nuclear Medicine Physics.

A. General considerations and format

The format of the examination process is similar to Part I and the information provided in section I A. applies.

B. Process of the examination

The IMPCB recommends that Part II certification examination consist of several components each component containing questions presented in one of the formats given above. Examples for this are provided in the appendix to the present document.

National or regional bodies seeking IMPCB accreditation would be expected to decide on the format used for their certification examination and present their proposed examination format to the IMPCB for evaluation. Upon receiving an IMPCB accreditation, the certification body would be obliged to make examination candidates fully aware of the examination format and rules governing marking of the examination papers. The IMPCB recommends that Part II of the IMPCB-accredited certification examination contain several sections, each section with questions presented in one or more of the formats listed above.

Typical duration of the Part II IMPCB-accredited written examination will be 3 – 4 hours.

C. Subjects that may be covered in the Part II examination shall be as follows

As for Part I of the examination these are separated in required knowledge and skills.

C.1. RADIATION ONCOLOGY MEDICAL PHYSICS

Knowledge
1. Explain in detail the statutory and institutional requirements for Medical Physics Services and the roles of the Medical Physicist, MPE, RPE and RPO in the establishment and management of systems for effective clinical use of medical devices and radiation protection of patient/staff/public in Radiation Oncology.
2. Interpret qualitatively and quantitatively anatomical and functional 2D/3D images from the various imaging modalities and recognise specific anatomical, functional and pathological features to a level necessary to be able to contribute effectively to the work of the Radiation Oncology team.
3. Describe the perspectives of the patient and other healthcare professionals in the Radiation Oncology team.
4. Explain in detail the design and functioning of medical devices used in Radiation Oncology and the design variables which impact device performance indicators and clinical effectiveness and including:
a. external beam devices: kV therapy devices, cobalt units, medical linear accelerators (linacs) and other systems for MV X-ray / gamma-ray /electron beams (tomotherapy devices, robotic linacs, mobile linacs, intra-operative radiation oncology devices, gamma knife, cyberknife), cyclotrons and synchrotrons (protons and heavier ion beams) and brachytherapy afterloading systems,
b. imaging devices: e.g., EPID, kV, CBCT, in-room CT,
c. treatment planning system software and calculation algorithms.

5. Explain in detail and quantitatively methods for quality control of medical devices in Radiation Oncology, including methods for acceptance testing and commissioning.

6. Explain in detail and quantitatively dose-bioeffect relationships relevant to Radiation Oncology.

7. Describe quantitatively and in detail the process and practical implementation of patient/occupational/public risk assessments, dose optimization and limitation in Radiation Oncology.

8. Discuss ethical issues related to the protection of patients and volunteers in Radiation Oncology research.


10. Describe present and envisaged future developments of medical devices and protection from associated ionising radiations in Radiation Oncology.

11. Explain pedagogical methods used for the training of other healthcare professionals in patient and personal protection in Radiation Oncology.

12. Explain in detail and quantitatively:
   a. the physical principles, capabilities and limitations of the different external beam irradiation techniques: 3D conformal, rotational techniques (conformal arcs, conformal dynamic arcs), non-coplanar techniques,
   b. the principles of beam and brachytherapy treatment planning systems and dose calculation and optimization algorithms,
   c. the use of conventional techniques to optimize dose distributions,
   d. recommended national / international absorbed dose measurement protocols based on absorbed dose in water/solid phantoms for photon and electron beams (including brief description/discussion of proton and heavier ion beams),
   e. the various approaches to in-vivo dosimetry for Radiation Oncology beams and discuss choice of appropriate sensors,
   f. the calibration chain for dosimetry sensors used in Radiation Oncology,
   g. theoretical and practical aspects of reference dosimetry for high-energy photons, electrons and brachytherapy sources,
   h. recommended methods for reference air kerma (RAK) determination for brachytherapy sources.

Skills

1. Operate at a basic level selected medical devices used in Radiation Oncology as appropriate to the role of a medical physicist.

2. Use selected methods for quality assurance/control of medical devices in Radiation Oncology (including TPS and manual/remote after-loading systems) and prepare a plan for acceptance testing and commissioning (including acquiring beam data for commissioning the TPS).

3. Use Information and Communication Technologies (ICT) standards and infrastructures applied in Radiation Oncology.

4. Apply quantitatively and in a detailed manner the concepts of justification, optimization and dose limitation with respect to patient / occupational-public protection in Radiation Oncology.
5. Use selected quantitative methods of patient and personal dosimetry and workplace / individual / environmental monitoring in Radiation Oncology and for the establishment of dose delivery prescriptions and dose constraints.
7. Design arrangements for prevention of accidents and incidents, preparedness and response in emergency exposure situations and disposal of any sources/waste in Radiation Oncology.
8. Prepare basic technical specifications for medical device procurement and new installation design in Radiation Oncology.
9. Survey at a basic level Radiation Oncology installations with regard to patient /occupational/public protection including the categorization of areas, classification of workers and any protective apparel and barriers.
10. Use a TPS for patient specific treatment plan generation and optimization and conventional techniques for creating optimized patient specific dose distributions.
11. Operate selected radiation measurement devices/detectors and interpret the results.
12. Select the most appropriate detector for measuring absolute and relative dose distributions in different irradiation conditions for photon and for electron beams.
13. Use the local recommended Code of Practice for the determination of absorbed dose to water from external radiotherapy photon beams.
15. Perform at a basic level brachytherapy source calibration.
16. Perform constancy checks on ionization chambers and calibrate diode dosimeters.
17. Perform at a basic level in-vivo dosimetry with appropriately chosen protocols and sensors including verification of the delivered dose at single points or planes (e.g., transit dosimetry using portal imaging).
18. Apply International, and national regulations for the transport, handling, storage and use of radioactive sources in Radiation Oncology.
19. Produce a basic plan for the design of new treatment, simulator and, sealed / unsealed source storage rooms with respect to occupational/public protection.
20. Use at a basic level selected immobilization (including stereotactic) devices for the immobilization of patients.
21. Use at a basic level selected conventional and CT/CBCT simulators for patient specific planning and plan verification.
22. Acquire multimodality imaging data and perform image fusion for target volume delineation and planning.
23. Archive, back-up and restore treatment plans.
24. Perform plan optimization and evaluation using uniformity criteria, constraints, DVHs and biological parameters (TCP, NTCP).
25. Use classical dose distribution calculation systems for LDR (e.g., Paris and Manchester systems) and extension to HDR, PDR.
26. Participate at a basic level in the verification of the different steps of treatment: patient positioning, target localisation, and dosimetric verification of the irradiation plan.
27. Perform independent monitor unit calculation for dosimetric verification of treatment plans.

C.2. DIAGNOSTIC AND INTERVENTIONAL RADIOLOGICAL PHYSICS

Knowledge:
1. Explain in detail statutory and institutional requirements for Medical Physics Services and the roles of the Medical Physicist, MPE, RPE and RPO in the establishment and management of systems for effective clinical use of medical devices and radiation protection of patient/staff/public in Diagnostic and Interventional Radiology.
2. Interpret qualitatively and quantitatively anatomical and functional 2D/3D images from the various imaging modalities and recognise specific anatomical, functional and pathological features to a level necessary to be able to contribute effectively to the work of the Diagnostic and Interventional Radiology team.

3. Describe the perspective of the patient and other healthcare professionals in the Diagnostic and Interventional Radiology team.

4. Explain in detail and quantitatively the design and functioning of medical devices used in Diagnostic and Interventional radiology and the design variables which impact device performance indicators and clinical effectiveness.

5. Explain in detail and quantitatively methods for quality assurance of medical devices in Diagnostic and Interventional Radiology, including methods for acceptance testing and commissioning.

6. Explain quantitatively and in detail dose-bioeffect relationships (particularly but not exclusively ionising radiation) relevant to Diagnostic and Interventional Radiology.

7. Describe in detail and quantitatively the process and practical implementation of patient/occupational/public risk assessments, dose optimization (including foetal risk) and limitation in Diagnostic and Interventional Radiology.

8. Discuss in detail ethical issues related to the protection of patients and volunteers from physical agents (particularly but not exclusively ionising radiation) in Diagnostic and Interventional Radiology research.


10. Describe present and envisaged future developments of medical devices and protection from associated physical agents in Diagnostic and Interventional Radiology.

11. Explain pedagogical methods used for the training of other healthcare professionals in patient and personal protection in Diagnostic and Interventional Radiology.

12. For each imaging modality (all variants of x-ray projection imaging, CT, ultrasound and MRI):
   a. explain quantitatively target image quality outcomes relevant to diagnostic effectiveness,
   b. explain quantitatively the physical properties of tissues which the device measures and images, including any variables impacting the value of these properties and associated tissue contrast,
   c. explain in detail image quality assessment criteria and the relationship with device performance indicators (e.g., unsharpness (LSR, PSF, LSF, MTF), noise (noise power spectra, noise propagation in image subtraction, NEQ, DQE), image contrast (CNR) etc,
   d. predict the effect on image quality outcomes, diagnostic accuracy, patient and occupational risk when changing scanning and image reconstruction parameters,
   e. explain in detail the structure of acquisition protocols, pre-processing of image data, mathematics of image reconstruction methods and post-processing of images,
   f. explain the strengths and limitations of the imaging modality and impact on diagnostic efficacy,
   g. define patient/occupational protection related indicators/quantities suitable for ensuring adherence to safety limits and reference levels (e.g., KAP, DLP, D, E, Hp, SAR, MSD) including methods for measurement or calculation,
   h. explain the physical basis of any contraindications in the use of the device and procedures for avoiding adverse events,
i. explain the impact on performance indicators arising from device malfunction, inappropriate protocol and device misuse including any artefacts arising from these and local procedures for reporting such malfunctions,

j. Apply quantitatively the theory of human image perception/observer performance to the optimization of image reading,

Skills:

1. Operate at a basic level selected medical devices used in Diagnostic and Interventional Radiology as appropriate to the role of a medical physicist.

2. Use selected methods for quality assurance/control of medical devices in Diagnostic and Interventional Radiology, and prepare a plan for acceptance testing and commissioning.

3. Use Information and Communication Technologies (ICT) standards and infrastructures applied in Diagnostic and Interventional Radiology.

4. Apply quantitatively and in a detailed manner the concepts of justification, optimization and dose limitation with respect to patient / occupational-public protection from physical agents in Diagnostic and Interventional Radiology.

5. Use selected quantitative methods of patient and personal dosimetry and workplace / individual / environmental monitoring in Diagnostic and Interventional Radiology and for the establishment of diagnostic reference levels and dose constraints.

6. Optimize imaging methods and acquisition parameters to fulfill clinical needs.

7. Optimize quantitatively patient / occupational physical agent protection in high risk practices in Diagnostic and Interventional Radiology.

8. Design arrangements for prevention of accidents and incidents, preparedness and response in emergency exposure situations and disposal of any sources/waste in Diagnostic and Interventional Radiology.

9. Prepare technical specifications for medical device procurement and new installation design in Diagnostic and Interventional Radiology.

10. Survey Diagnostic and Interventional Radiology installations with regard to patient/occupational/public protection from physical agents including the categorization of areas, classification of workers and any protective apparel and barriers.

11. For each imaging modality (x-ray projection imaging, CT, ultrasound and MRI):
   a. apply quantitative image processing techniques to increase the diagnostic value of images,
   b. identify possible causes of device malfunctioning, below target imaging quality and suggest appropriate action,
   c. design protective barriers, accessories and personal protective equipment with regard to occupational/public safety including shielding calculations.

C.3. NUCLEAR MEDICINE MEDICAL PHYSICS

Knowledge

1. Explain in detail statutory and institutional requirements for Medical Physics Services and the roles of the Medical Physicist, MPE, RPE and RPO in the establishment and management of systems for effective clinical use of medical devices and radiation protection of patient/staff/public in Nuclear Medicine.

2. Interpret qualitatively and quantitatively anatomical and functional 2D/3D images from the various imaging modalities and recognise specific anatomical, functional and pathological features to a level necessary to be able to contribute effectively to the work of the Nuclear Medicine team.

3. Describe the perspective of the patient and other healthcare professionals in the Nuclear Medicine team.
4. Explain in detail and quantitatively the design and functioning of medical devices used in Nuclear Medicine and the design variables which impact device performance indicators and clinical effectiveness.

5. Explain in detail and quantitatively methods for quality assurance of medical devices in Nuclear Medicine, including acceptance testing and commissioning.

6. Explain quantitatively and in detail dose-bioeffect relationships relevant to Nuclear Medicine.

7. Describe in detail and quantitatively the process and practical implementation of patient/occupational/public risk assessments, dose optimization (including foetal risk) and limitation in Nuclear Medicine.

8. Discuss in detail ethical issues related to the protection of patients and volunteers from ionising radiation in Nuclear Medicine research.


10. Describe present and envisaged future developments of medical devices and protection from associated ionising radiations in Nuclear Medicine.

11. Explain pedagogical methods used for the training of other healthcare professionals in patient and personal protection in Nuclear Medicine.

12. For each Nuclear Medicine imaging modality (gamma camera, SPECT, PET, hybrid systems):
   a. list and explain target image quality outcomes relevant to diagnostic effectiveness.
   b. explain in detail image quality assessment criteria and the relationship with device performance indicators
   c. predict the effect on image quality, diagnostic accuracy, patient and occupational risk when changing scanning and image reconstruction parameters and radiopharmaceutical.
   d. explain in detail the structure of acquisition protocols, pre-processing of image data, mathematics of image reconstruction methods and post-processing of images. Describe the influence of the reconstruction method and processing parameters used in PET/SPECT (e.g. cut-off frequency, number of iterations, number of subsets, post-filtering type and parameters) on activity measurements.
   e. apply quantitative image processing techniques to increase the diagnostic value of images,
   f. explain the strengths and limitations of the imaging modality and impact on diagnostic efficacy,
   g. define patient/occupational protection related indicators/quantities suitable for ensuring adherence to safety limits and reference levels including methods for measurement or calculation.
   h. explain the physical principles underpinning the methods for the prevention of contamination, protective barriers, accessories and personal protective equipment with regard to occupational/public safety including shielding calculations (including PET systems and cyclotrons).
   i. identify possible causes of device malfunctioning, below target imaging quality and suggest appropriate action in simple situations.

13. Describe and explain in detail the structure of a radiopharmacy with particular reference to radiation protection and quality control of radiopharmaceuticals.

14. Explain in detail the structure, functioning and use of devices required within the context of patient dosimetry e.g., well counters, dose calibrators.

15. Explain the MIRD scheme and the fundamental characteristics and limitations of the formalism, and how this governs its usage.

16. Explain the fundamental limitations of dosimetry at the organ level, for instance in deriving tumour dosimetry, taking into account activity and density heterogeneities.
17. Describe how Dose-Volume-Histograms or isodose curves are calculated and what results should be provided.
18. Describe how diagnostic and therapeutic exposures are managed in the context of Nuclear Medicine, including optimization of dose through prescription of recommended administered activities and protocols.
19. Describe the process and practical implementation of radiation risk assessments in the context of Nuclear Medicine arising from both external and internal sources of exposure.
20. Describe the key considerations when designing a new facility to optimise radiation safety of workers and the public including radionuclide therapy, and radiopharmaceutical production and PET cyclotron.
21. Describe the requirements for regulatory compliance with respect to the management and use of sealed and unsealed radiation sources including security considerations, requirements for storage, shielding, record-keeping, disposal, transportation and audit.
22. Explain the nature and sources of internal and external radiation exposure and the relevant dose limits in Nuclear Medicine for the worker, including extremity doses and dose limits for pregnant and lactating workers, and young workers, and the public, and dose constraints for comforters and carers.

Skills

1. Operate at a basic level selected medical devices used in Nuclear Medicine as appropriate to the role of a medical physicist and adjust equipment settings (e.g., choice of energy windows, collimators, scan duration, count statistics) for optimum activity results.
2. Use selected methods for quality assurance/control of medical devices in diagnostic Nuclear Medicine, and prepare a plan for acceptance testing and commissioning.
3. Use Information and Communication Technologies (ICT) standards and infrastructures applied in Nuclear Medicine.
4. Apply quantitatively and in a detailed manner the concepts of justification, optimization and dose limitation with respect to patient / occupational-public protection from external radiation and internal contamination in Nuclear Medicine.
5. Use selected quantitative methods of patient and personal dosimetry and workplace / individual / environmental monitoring in Nuclear Medicine and for the establishment of recommended activities and dose constraints.
7. Design arrangements for prevention of accidents and incidents, preparedness and response in emergency exposure situations and disposal of any sources/waste in Nuclear Medicine.
8. Prepare technical specifications for medical device procurement and new installation design in Nuclear Medicine.
9. Survey at a basic level Nuclear Medicine installations with regard to patient/occupational/ public protection including the prevention of contamination, categorization of areas, classification of workers and any protective apparel and barriers.
10. For each imaging modality (gamma camera, SPECT, PET, hybrid systems):
   a. apply quantitative image processing techniques to increase the diagnostic value of images,
   b. identify possible causes of device malfunctioning, below target imaging quality and suggest appropriate action in simple situations,
   c. design methods for the prevention of contamination, protective barriers, accessories and personal protective equipment with regard to occupational/public safety including shielding calculations.
   d. Extract parametrical information
11. Design optimal dosimetry protocols and calculation procedures for molecular radiotherapies.
12. Perform dosimetric calculations using the MIRD formalism.
13. Determine whole body, organ and effective doses using tools such as OLINDA.
PART III:  
Requirements for successful completion of Part III of the exam

The following are suggested Oral Examination processes and Accreditation Requirements as compiled by Accreditation subcommittee III charged with providing guidance on and develop additional requirements for the IMPCB oral examination and accreditation process. The nature of this part of the examination differs from the two previous ones as it does require the examiners and the candidates to meet.

A. General considerations

In developing such requirements, the committee took the following into consideration:

1. Knowing that education and training resources may vary significantly between countries and regions, every effort will be made to provide a credentialing process that is amenable to work with the variety of medical physics environments without compromising the integrity of the board certification objectives.

2. A candidate enrolment in training to prepare for the oral boards, requires the candidate successful completion of Parts I and II of the board training and exams requirements.

3. The Oral exam will mainly test the candidate clinical skills and how to operate as an independent and safe medical physicist.

4. There will be three Oral Exam certification boards covering the three clinical medical physics specialties currently under consideration, namely: Radiation Oncology, Diagnostic and Interventional Radiological, and Nuclear Medicine Medical Physics.

B. Process of examination

There are five categories in this exam, details of which will depend on the sub-speciality (radiation therapy or diagnostic imaging physics), as outlined in C.4

The total exam duration shall be 150 minutes (5 questions per category, 6 minutes per question, total of 30 minutes per category) divided equally between the panels and panel members. The exam can be conducted in one full session or split the exam time into two successive sessions, depending on the exam format.

B.1. The oral exam shall be conducted in one of the following formats:

1. A single examination panel including 3-5 examiners asking competency questions listed in the five categories listed in C.4.

OR

2. Multiple examination panels like one-on-one (need five examiners) or two-on-one (need 4 examiners). One of the examiners shall be selected as the exam Panels chair. All panels will ask competency questions on all five categories listed in C.4.

3. Examiners in each panel will alternate on asking the questions. They should initially average the scores given per question in each category then discuss the candidate performance and decide on Pass, Fail or Conditioned.
4. A “Conditioned” candidate is only required to repeat the failed category. Candidates failing two or more categories fail the examination and must repeat the entire exam.

5. Pass/Fail per category: one example of a scoring system per question asked is 1-5 with 1 being poor performance and 5 being outstanding performance. The Pass score for each category shall be an average of 3 or above. A score of 2 in one category can be raised to 3 IF the examination panel discussion leads to such a conclusion. The panel can raise only one category from 2 to 3. A 1 average score in any category cannot be raised. All averages will be truncated, i.e. average of 2.9 becomes 2.

C. Specifics:

1. Additional training requirements for a candidate to be eligible for admission to the specialty oral examination means: training in an IMPCB recognized accredited program to obtain specific competences in a specialty area.

2. The duration over which such competences are obtained shall be two years.

3. The IAEA education of medical physicists program, IAEA TCS-37, TCS-47, TCS-50 and the AAPM report 197 and 249 on the same subject shall be considered when outlining the following details:
   a. The type and extent of supervision and guidance needed during the clinical training.
   b. Suggestion of specific implementation steps like the use of didactic courses (class room), tests, research, thesis, residency, paper publication, lab work, specific clinical tasks, specific clinical skills, rotation in other specialties
   c. The extent of each competency in length and depth, and time to be spent to cover each of the competences in the two year program.

4. The list of competences a candidate should obtain for each medical physics specialty includes the following categories. It is expected that each specialty will select and configure the appropriate items in each category that are relevant to that specialty.
   a. Patient-Related Measurements
      Calculation of dose from photon and particle beams and radionuclide sources; radiotherapy treatment planning; physical factors affecting dose (e.g., beam intensity, field size, depth, thickness, filtration, half-life, screens, grids, concentration, etc.); special techniques and devices (e.g., rotational therapy, stereotactic radiosurgery; IMRT; wedge filters, infusion techniques, grids, radiography, fluoroscopy, mammography, tomography, CT, ultrasound, computers and their applications, etc.); preparation of applicators; low-dose-rate (LDR) and high-dose-rate (HDR) brachytherapy; in vivo and in-phantom dose measurements; and related subjects.
   b. Image Acquisition, Processing and Display
      Principles of and techniques for image acquisition; image formation; digital imaging; computer-based image reconstruction; methods for image display; image analysis; image processing, image enhancement, fusion and segmentation; image artefacts; modulation transfer function; signal-to-noise
ratio; informatics; picture archiving and communication systems; and related subjects.

c. Calibration, Quality Control and Quality Assurance
   Characteristics and use of calibration equipment; measurements of radiation quantity and quality; calibration and evaluation of ionizing and nonionizing radiation sources and installations; calibration and evaluation of measuring, recording, and imaging devices; acceptance testing, commissioning, quality control and quality assurance; and related subjects.

d. Equipment
   Principles and properties of radiation generating equipment; radiation sources; radiation receptors; radiation therapy equipment; diagnostic radiological equipment; nuclear medicine equipment; ultrasound equipment; nuclear magnetic resonance equipment; and related subjects.

e. Radiation Protection and Patient Safety
   Time, distance and shielding; workload, use and occupancy factors; shielding design for primary, scatter, and leakage radiation; barrier calculation; report preparation; air concentrations of radioactivity; department design; radiation standards and units; radiation protection principles; radiation regulations and requirements; responsibilities of the radiation protection office; radiation surveys in diagnostic radiology, nuclear medicine, and radiation therapy; characteristics of survey equipment; evaluation of radiation hazards; personnel monitoring; and related subjects.
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B. Specialties

1. RADIATION ONCOLOGY MEDICAL PHYSICS


W. Hendee, G.S. Ibbott, Radiation Therapy Physics (Mosby, St. Louis, MO, USA, 1996)


Podgorsak et al. Radiation Oncology Physics: A handbook for teachers and students. IAEA Vienna 2005

J. Van Dyk (Ed), The Modern Technology of Radiation Oncology (Medical Physics Publishing, Madison, WI, USA, 1999)

2. DIAGNOSTIC MEDICAL IMAGING PHYSICS


IAEA, Diagnostic Radiology Physics, Vienna, Austria, 2014


P. Sprawls, Physical Principles of Medical Imaging (Medical Physics Publishing, Madison, WI, USA, 1995)
3 NUCLEAR MEDICINE


S.R. Cherry, J.A. Sorenson, M.E. Phelps, Physics of Nuclear Medicine, 4th edn (Saunders, Philadelphia, PA, USA, 2012)

IAEA, Physics of Nuclear Medicine, Vienna, Austria, 2014

Appendices:

1. Notes on multiple choice questions for part I and II of the medical physics written certification examination

Typical examinations based on multiple choice (MC) questions employ several question types to test the breadth and depth of candidate’s knowledge and skills. Most frequently multiple choice exam questions fall into one of the following three MC question types:

I. Traditional multiple choice question is referred to as Type A multiple choice question and consists of an item stem and five plausible answers containing one correct answer and four distractors.

II. Multiple True – False multiple choice question is referred to as Type K multiple choice question and tests the candidate’s in-depth understanding of several aspects of a concept, process, or procedure.

III. Matching multiple choice question is referred to as Type B multiple choice question and consists of a set of directions, a set of 5 premises, i.e., items to be matched, as well as a set of 4 options associated with the premises.

Many recommendations, some of dubious value, are available on strategies for writing MC examinations. They are often presented in the form of rules of thumb that border on gambling or guesswork and have little or no connection with the examination format and examination material. For example, assuming that the correct answer to a MC question is the answer option with the longest text or with the most scientific-sounding language or simply option B out of five possible options is neither an advisable nor a reliable MC examination strategy. The candidates must understand that the basic requirements for doing well in a MC exam are: (i) having solid background in examination material, (ii) studying hard, (iii) knowing the subject material, and (iv) understanding the subject material.

Some useful strategies for candidates writing MC examinations are:

1. Carefully read all instructions provided with the examination paper.
2. Determine how much time you have for each MC question, leaving some time at the end of exam for verification of answers.
3. Read each MC question carefully and try to anticipate the correct answer before getting distracted by all the possible options. Remember that all distractors generally look plausible, yet among the five options there is only one correct or best answer.
4. For a given MC question read all the possible options before committing yourself to an answer.
5. For MC questions involving calculations verify the decimal points as well as the units of physical quantities.
6. Start the MC examination with questions that you find easy and return to difficult questions once you run out of the easy ones.
7. There is no adequate substitute for knowing the correct answer to a MC question.
8. At the beginning of the examination verify whether or not penalty is assigned for incorrect answers and proceed accordingly.
9. Relying on lucky guesses or mystical “rules of thumb” is not a good MC examination strategy, especially, if a penalty is assigned for incorrect answers.
10. In MC examinations graded without a penalty for incorrect answers, making an educated guess to a difficult question is an acceptable strategy.
11. Be prepared for the MC examination emotionally, physically, as well as intellectually.
12. Keep calm during the examination.
1.b Notes on certification examination models based on random choice questions from an examination booklet.

While the format of multiple choice questions is appropriate for both part I. and part II of the written certification examinations, part II. examination can also be given in a format based on a random choice from a large question bank available to candidates several months prior to the examination session. In this model, the examination committee of the national or regional certification body determines the random choice of a predetermined number of long questions from the examination booklet. The long questions usually consist of a combination of various components, all components dealing with a specific aspect of a broad medical physics subject and falling into one of the following categories: short question, essay type question, or computational question.

Excellent examples of random choice long medical physics questions for several specialties of medical physics as well as examination rules are available from the Canadian College of Physicists in Medicine (CCPM) on-line at: www.ccpm.ca
2. Examples for questions in Part I:

a) Multiple Choice (MC)

I. EXAMPLES OF TRADITIONAL MULTIPLE CHOICE QUESTION:
(circle the appropriate answer A., B., C., D., or E.)

Example 1: [Correct answer is option C. (0.44 MeV) obtained from the Compton graph]
A mono-energetic 1 MeV photon beam has a Compton interaction with a lead absorber. The mean energy transferred to electrons in lead is:

A. 1 MeV
B. 0.511 MeV
C. 0.440 MeV
D. 0.255 MeV
E. negligible

Example 2: [Correct answer is option B. (13.6 eV) obtained from theory of Bohr atom]
The binding energy of a n = 2 electron in a singly ionized helium atom is:

A. 3.4 eV
B. 13.6 eV
C. 27.2 eV
D. 54.4 eV
E. 108.8 eV

Example 3: [Correct answer is option E. based on alpha particle scattering on atomic nuclei, Geiger-Marsden experiment, and Rutherford model of the atom]
Rutherford scattering refers to an interaction between:

A. energetic electron and orbital electron.
B. photon and loosely bound electron.
C. neutron and heavy nucleus.
D. photon and nucleus.
E. alpha particle and heavy nucleus.
Example 4: [Correct answer is option B.]
Fluorescence yield is defined as:

A. number of photons emitted in a bremsstrahlung interaction.
B. number of characteristic photons emitted per vacancy in atomic shell.
C. number of Auger electrons emitted per vacancy in atomic shell.
D. number of photons emitted in gamma decay
E. number of electrons emitted in internal conversion.

Example 5: [Correct answer is option A.]
In an air-filled ionization chamber used in radiation dosimetry:

A. positive ions and negative ions are collected.
B. positrons and electrons are collected.
C. positive ions and electrons are collected.
D. neutral atoms are collected.
E. characteristic photons and Auger electrons are collected.

Example 6. Which statement best describes the phenomenon of pair production?

A. The electrons and positrons are emitted at 180° to each other.
B. Positrons and antineutrinos are produced when the interactions occur.
C. Photons with energies greater than 1.02 MeV are necessary for the interactions to occur.
D. The total energy of the incident photon is evenly divided between the kinetic energy of the pair of particles.

Example 7. The organ marked X in the image below is the:

A. Liver
B. Spleen
C. Kidney
D. Aorta
Example 8. Which of the following is non-probability sampling?

A. Snowball sampling  
B. Random sampling  
C. Cluster sampling  
D. Stratified sampling

II. EXAMPLES OF TRUE – FALSE MULTIPLE CHOICE QUESTIONS:
(circle the appropriate answer A., B., C., D., or E.)

Example 1: [Correct answer is option E. based on the Bohr theory of the atom]

The validity of the Bohr/Rutherford atomic model is supported by results from the following experiments:

(1) Franck-Hertz experiment.  
(2) Davisson-Germer experiment.  
(3) Moseley experiment.  
(4) absorption and emission spectra of gases.

A. all are correct.  
B. (1) and (4) only are correct.  
C. (1), (2), and (4) only are correct.  
D. (2) and (3) only are correct.  
E. (1), (3) and (4) only are correct.
Example 2: [Correct answer is option B. Note: in nuclear pair production no electronic vacancies are produced in atomic shells]

Electronic vacancies are produced in atomic shells through various effects, such as:

1. photoelectric effect.
2. nuclear pair production.
3. electron capture.
4. Auger effect.

A. all are correct.
B. (1), (3), and (4) only are correct.
C. (1) and (2) only are correct.
D. only (1) is correct.
E. (3) and (4) only are correct.

Example 3: [Correct answer is option D. The emitted electron is called an Auger electron and it is emitted with energy of 58 keV].

The K, L, and M energy levels in a hypothetical multi-electron atom are −80 keV, −20 keV and −2 keV, respectively. A vacancy is produced in the K shell and is filled by an electron from the L shell and the L − K transition is followed by an emission of an M shell electron.

1. Emitted M-shell electron is called an internal conversion electron.
2. Emitted M-shell electron is called an Auger electron.
3. Emitted M-shell electron is called a Compton electron.
4. M-shell electron is emitted with energy of 60 keV.
5. M-shell electron is emitted with energy of 58 keV.

A. only (1) is correct.
B. (1) and (4) only are correct.
C. (2) and (4) only are correct.
D. (2) and (5) only are correct.
E. only (4) is correct.

III EXAMPLES OF MATCHING MULTIPLE CHOICE QUESTIONS:
Example 1: [Correct answers are as follows: for (001) – option E.; for (002) – option B.; for (003) – option A.; and for (004) – option D.]

Match each year listed in (001) through (004) with appropriate discovery listed in A. through E.

A. electron by Thomson.
B. natural radioactivity by Becquerel.
C. neutron by Chadwick.
D. nuclear fission by Hahn, Strassmann, Meitner, and Frisch.
E. x rays by Röntgen.

Example 2: [Correct answers are as follows: for (001) – option D.; for (002) – option A.; for (003) – option C.; and for (004) – option E.]

Match the given interaction listed in (001) through (004) with the appropriate effect listed in A. through E.

A. photoelectric effect.
B. Rutherford scattering.
C. bremsstrahlung.
D. Compton scattering.
E. nuclear pair production.
(003) electron interaction with nucleus.  A.  B.  C.  D.  E.
(004) photon interaction with nucleus.  A.  B.  C.  D.  E.

Example 3: [Correct answers are as follows: for (001) – option A.; for (002) – option D.; for (003) – option B.; and for (004) – option E.]

Match the values listed in (001) through (004) with appropriate parameter listed in A. through E.

A. classical radius of the electron.
B. Compton wavelength of the electron.
C. distance of closest approach for an 8 MeV alpha particle undergoing Rutherford scattering on a gold (A = 197) foil.
D. radius of gold nucleus.
E. radius of hydrogen atom.

(001) 2.82 fm.  A.  B.  C.  D.  E.
(002) 5.82 fm.  A.  B.  C.  D.  E.
(003) 0.024 A.  B.  C.  D.  E.
(004) 0.53 A.  B.  C.  D.  E.

Example 4: [Correct answers are as follows: for (001) – option A.; for (002) – option C.; for (003) – option E.; and for (004) – option B.]

Match the major linac components listed in (001) through (004) with appropriate linac operational system listed in A. through E. below:

A. injection system.
B. radiofrequency power generation system.
C. beam transport system.
D. acceleration waveguide.
E. beam monitoring system.

(001) electron gun.  A.  B.  C.  D.  E.
(002) bending magnet.  A.  B.  C.  D.  E.
b. Short answer:

1. Distinguish between absorbed dose, equivalent dose and effective dose.

2. Explain the sharp discontinuities (absorption edges) in the variation of the photoelectric component of the mass linear attenuation coefficient with incident photon energy.

3. The dead time of a GM counter is 100 μs. Find the true counting rate if the measured counting rate is 12,000 counts per minute.

c. Essay type:

The mission statement of the medical physicist can be stated as follows: “Medical Physicists will contribute to maintaining and improving the quality, safety and cost-effectiveness of healthcare services through patient-oriented activities requiring expert action, involvement or advice regarding the specification, selection, acceptance testing, commissioning, quality assurance/control and optimised clinical use of medical devices and regarding patient protection from associated physical agents; all activities are to be based on current best evidence or own scientific research when the available evidence is not sufficient. The scope includes risks to volunteers in biomedical research, carers and comforters; and occupational/public when impacting patient safety (EC Guidelines on the Medical Physics Expert project)” Explain the above mission statement (in particular the terms in italics) and discuss its application to ONE of the specialties of medical physics i.e., EITHER Diagnostic and Interventional Radiology OR Radiation Oncology OR Nuclear Medicine.

d. Computational type:

1. This question is about gas-filled detectors

   (a) The diagram below shows the variation of output pulse size from a gas-filled ionization detector with variation in the bias voltage. Describe and explain the main regions of the diagram and their use.
(b) The dead time of a GM counter is 100 s. Find the true counting rate if the measured counting rate is 12,000 counts per minute.

(c) An ionization chamber and an electrometer are used to carry out measurements on an electron beam of energy 0.50 MeV. Assuming that the chamber is being used in the saturation region and that all photons produced are stopped within the chamber, calculate the number of incident electrons per second that would produce an electrometer reading of 200 pA given that the ionization energy $W$ of the gas is 35 eV.

2. Calculate the total effective dose for a chest x-ray of a female patient from the following data:

Absorbed dose at the entrance point to the patient’s skin (entrance skin absorbed dose) = 500 Gy

<table>
<thead>
<tr>
<th>Organ/tissue</th>
<th>Absorbed dose to organ / tissue as percentage of entrance skin absorbed dose (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>gonads</td>
<td>2</td>
</tr>
<tr>
<td>breast</td>
<td>2</td>
</tr>
<tr>
<td>bone marrow (red)</td>
<td>1</td>
</tr>
<tr>
<td>Organ / Tissue</td>
<td>Tissue Weighting Factor</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Bone-marrow (red), Colon, Lung, Stomach, Breast, Remainder tissues*</td>
<td>0.12</td>
</tr>
<tr>
<td>Gonads</td>
<td>0.08</td>
</tr>
<tr>
<td>Bladder, Oesophagus, Liver, Thyroid</td>
<td>0.04</td>
</tr>
<tr>
<td>Bone surface, Brain, Salivary glands, Skin</td>
<td>0.01</td>
</tr>
</tbody>
</table>

* Remainder tissues: Adrenals, Extrathoracic (ET) region, Gall bladder, Heart, Kidneys, Lymphatic nodes, Muscle, Oral mucosa, Pancreas, Small intestine, Spleen, Thymus, Prostate (♂), Uterus/cervix (♀)

3. Distinguish between a Gaussian, lognormal and Poisson distribution commenting on the circumstances of their use in medical physics.

The table below gives the number of background counts x for 50 intervals each of 1 minute duration in a nuclear medicine facility.

Calculate the mean count

Calculate the measured fractional frequencies

For each count value x, calculate the expected fractional frequency assuming a Poisson distribution with the mean calculated above

Draw a scatter diagram with measured fractional frequency on the x-axis and the expected fractional frequency based on the assumption of a Poisson distribution on the y-axis. Comment on the result.

<table>
<thead>
<tr>
<th>x</th>
<th>Measured frequency (number of intervals with the given count)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>21</td>
</tr>
<tr>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>
4. The following question involves an application of Laplacian filtering in image processing.

(a) Laplacian filtering can be used to detect edges in an image. Specify a Laplacian filter mask and compute the image that results when Laplacian filtering is applied to the image $B$ where

\[
B = \begin{pmatrix}
240 & 243 & 220 & 200 & 50 \\
230 & 223 & 215 & 53 & 45 \\
228 & 225 & 59 & 54 & 45 \\
214 & 61 & 54 & 49 & 42
\end{pmatrix}
\]

The border pixels of the resulting image can be ignored.

(b) Describe how the performance of Laplacian filtering for edge detection compares to that of first derivative filters such as Prewitt or Sobel operators.

(c) Write a MATLAB program that filters an image $B$ using a Laplacian filter. The program must provide plots of the resulting image as well as its centred magnitude and phase spectrum.

2. Examples for questions in Part II:

To come

Comment: Good examples for multiple choice questions: [http://www.theabr.org/ic-rp-sample](http://www.theabr.org/ic-rp-sample)

3. Examples for questions in Part III:

To come