REFERENCE	COMMISSION'S PROPOSAL	WG PROPOSED VERSION	REASON FOR CHANGE
Chapter II, Definitions	[logically, non-alphabetically ordered list]	[put terms in alphabetical list, as reported in annex 1]	List in alphabetical order has an increased readibility and usefulness with respect to logical order
Chapter II, Definitions	[NOT PRESENT BUT FREQUENTLY REMINDED IN THE TEXT]	Medical surveillance: is the whole of medical procedures for the early identification of adverse effects due to ionizing radiation, or conditions, if any, that could present an increased risk of adverse radiation health effects related to the task being performed, and for the assurance, so far as possible, of safe and healthful working conditions for every working man and woman.	Although already recalled in art.44, the Working Group deems necessary to better specify content and objectives of medical surveillance
Chapter II, Definitions	[NOT PRESENT]	approved medical practitioner: a medical practitioner responsible for the medical surveillance of exposed workers, whose capacity to act in that respect is recognized by the competent authorities.	The Working Group deems necessary to define the approved medical practitioner, a figure already present in the Italian radiation protection Legislation as a legacy of Directive 96/29/EURATOM.

REFERENCE	COMMISSION'S PROPOSAL	WG PROPOSED VERSION	REASON FOR CHANGE
Definition (40)	Medical physics expert means an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence to act is recognised by the competent authorities;	Medical physics expert means an individual having knowledge, training and experience needed to carry out physical and dosimetric tests to assess performance of radiological equipment and to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence to act is recognised by the competent authorities	The role of the MPE needs to be better defined, according to the Working Group.
Definition (42)	Radiation protection expert means an individual having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose capacity to act is recognised by the competent authorities;	Radiation Protection Expert means an individual having the knowledge, training and experience needed to carry out physical, technical or radiochemical tests enabling doses to be assessed and to give radiation protection advice in order to ensure the effective protection of individuals, and whose capacity to act is recognised by the competent authorities	The Working Group, recognizing that possibly, in Italy, the RPE will be responsible for dose evaluations, as is the case for the Qualified expert today, feels that its definition must clearly state this task

REFERENCE	COMMISSION'S PROPOSAL	WG PROPOSED VERSION	REASON FOR CHANGE
Definition (44)	Occupational health service means a health professional or body having competence for the medical surveillance of exposed workers and whose capacity to act in that respect is recognized by the competent authorities	Occupational health service means a health professional, named approved medical practitioner, or body, having the competence for medical surveillance of workers, whose capacity to act, in that respect, it is recognized by the competent authorities.	The Working Group deems necessary to better specify the role of the approved medical practitioner, a figure already present in the Italian radiation protection Legislation, having a very specific role and responsibility: it is a legacy of Directive 96/29/EURATOM.
Definition (49)	Practical aspects of medical exposure procedures means the physical conduct of a medical exposure and any supporting aspects including handling and use of medical radiological equipment, and the assessment of technical and physical parameters, including radiation doses, calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, and image processing as carried out by, among others, radiographers and technicians in nuclear medicine and radiotherapy;	Practical aspects of medical exposure procedures means the physical conduct of a medical exposure and any supporting aspects including handling and use of medical radiological equipment, and the assessment of technical and physical parameters, including radiation doses, calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, and image processing as carried out by radiographers and technicians in nuclear medicine and radiotherapy and, where appropriate, by medical physics expert	The Working Group stresses that dose assessment is not a duty assigned to radiology or nuclear medicine technicians, but to the MPE. The Working Group, recognizing that MPE is responsible for dose evaluations, including physical measurements for evaluation of the dose delivered to the patient, give advice on medical radiological equipment feels that this definition have to take into account these tasks

REFERENCE	COMMISSION'S PROPOSAL	WG PROPOSED VERSION	REASON FOR CHANGE
Art. 11 (title)	Protection of pregnant women	Protection of pregnant women and newborns	The Working Group considers that this article is certainly devoted to the protection of the mother, but mostly of the child.
Art. 15	Member States shall establish education, training and retraining to allow the recognition of radiation protection experts, medical physics experts, occupational health services, and dosimetry services.	Member States shall establish education, training and retraining to allow the recognition of radiation protection experts, medical physics experts, approved medical practitioner/ occupational health services, and dosimetry services.	According to the Working Group, the role of the approved medical practitioner needs to be highlighted, in view of the existing Italian legislation.
Art. 19, point 5	Member States shall ensure the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.	Member States shall ensure the introduction of a course in radiation physics, radiation biology and radiation protection in the basic curriculum of medical and dental schools.	The Working Group esteems that not only a course in radiation protection is needed, but also in radiation physics and biology, which provide a larger view on the nature of radiation and its interaction with human cells and tissues.
Art. 28, point 2, letter e)	safety assessment of the activities and the installation in order to:	safety assessment, following the advice of a Radiation Protection Expert, of the activities and the installation in order to:	The role of the RPE needs to be better defined, according to the Working Group.

REFERENCE	COMMISSION'S PROPOSAL	WG PROPOSED VERSION	REASON FOR CHANGE
Art. 33, point 3	For undertakings operating aircraft where the effective dose to the crew from cosmic radiation is liable to exceed 6 mSv per year, the relevant requirements set out in this Chapter shall apply. Where the effective dose to the crew is less than or equal to 6 mSv per year and liable to be above 1 mSv per year, the competent authorities shall at least require undertakings to keep exposures under review, taking into account the potential for doses to change over time or as a result of changes in the work arrangements. The undertakings shall take appropriate measures, in particular: (a) to assess the exposure of the crew concerned; (b) to take into account the assessed exposure when organising working schedules with a view to reducing the doses of highly exposed crew; (c) to inform the workers concerned of the health risks their work involves and their individual dose.	[TO DELETE]	The Working Group notes that this arrangement is not ensuring proper radiological and medical surveillance to aircraft workers.

REFERENCE	COMMISSION'S PROPOSAL	WG PROPOSED VERSION	REASON FOR CHANGE
Art. 38, point 1, letter a)	category A: those exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv per year for skin and extremities;	[No modification foreseen]	The Working Group notes that every single exposed worker, who is classified for radiological risk at the lens of the eye would be classified as category A worker, according to this definition. A revision of population (15 mSv) and occupational (20 mSv) dose limits for the lens of the eye is needed.
Art. 43, point 2	Member States shall facilitate the exchange among competent authorities, occupational health services, radiation protection experts, or dosimetry services within the Union of all relevant information on the doses previously received by a worker in order to perform the medical examination prior to employment or classification as a category A worker pursuant to Article 44 and to control the further exposure of workers.	Member States shall facilitate the exchange among competent authorities, occupational health services, radiation protection experts, or dosimetry services within the Union of all relevant information on the doses previously received by a worker in order to perform the medical examination prior to employment or classification as exposed worker pursuant to Article 44 and to control the further exposure of workers.	The Working Group considers unnecessary to restrict medical surveillance to Category A workers only, and scientifically not founded. (see annex 1)
Art. 44, point 2	The medical surveillance of category A workers shall be the responsibility of (...)	The medical surveillance of exposed workers shall be the responsibility of (...)	The Working Group considers unnecessary to restrict medical surveillance to Category A workers only, and scientifically not founded.(see annex 1)

REFERENCE	COMMISSION'S PROPOSAL	WG PROPOSED VERSION	REASON FOR CHANGE
Art. 44, point 3	Medical surveillance shall include: (a) A medical examination prior to employment or classification as a category A worker to determine the worker's fitness for a post as a category A worker for which the worker is being considered. (b) Periodic reviews of health. The state of health of all exposed category A workers shall be reviewed (...)	Medical surveillance shall include: (a) A medical examination prior to employment or classification as exposed worker to determine the worker's fitness for a post as exposed worker for which the worker is being considered. (b) Periodic reviews of health. The state of health of all exposed workers shall be reviewed (...)	The Working Group considers unnecessary to restrict medical surveillance to Category A workers only, and scientifically not founded. (see annex 1)
Art. 45	The following medical classification shall be established with respect to fitness for work as a category A worker:	The following medical classification shall be established with respect to fitness for work as exposed worker:	The Working Group considers unnecessary to restrict medical surveillance to Category A workers only, and scientifically not founded. (see annex 1)
Art. 46	No worker may be employed or classified for any period in a specific post as a category A worker if medical surveillance establishes that the worker is unfit for that specific post.	No worker may be employed or classified for any period in a specific post as an exposed worker if medical surveillance establishes that the worker is unfit for that specific post.	The Working Group considers unnecessary to restrict medical surveillance to Category A workers only, and scientifically not founded. (see annex 1)

REFERENCE	COMMISSION'S PROPOSAL	WG PROPOSED VERSION	REASON FOR CHANGE
Art. 47	1. A medical record shall be opened for each category A worker and kept up to date so long as the worker remains a worker in that category. Thereafter, it shall be retained until the individual has or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure to ionizing radiation. 2. The medical record shall include information regarding the nature of the employment, the results of the medical examinations prior to employment or classification as a category A worker, the periodic reviews of health and the record of doses required by Article 41.	1. A medical record shall be opened for each exposed worker and kept up to date as long as the worker remains exposed. Thereafter, it shall be retained until the individual has or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure to ionizing radiation. 2. The medical record shall include information regarding the nature of the employment, the results of the medical examinations prior to employment or classification as an exposed worker, the periodic reviews of health and the record of doses required by Article 41.	The Working Group considers unnecessary to restrict medical surveillance to Category A workers only, and scientifically not founded. (see annex 1)
Art. 51, point 1, letter a)	only category A workers as defined in Article 38 may be subject to such exposures;	[TO DELETE]	The Working Group considers unnecessary to restrict the medical authorized exposure to Category A workers only, and scientifically not founded.(see annex 1)

REFERENCE	COMMISSION'S PROPOSAL	WG PROPOSED VERSION	REASON FOR CHANGE
Art. 51, point 1, letter c)	the undertaking shall carefully justify such exposures in advance and thoroughly discuss them with the voluntary workers, their representatives, the occupational health services or the radiation protection expert;	the undertaking shall carefully justify such exposures in advance and thoroughly discuss them with the voluntary workers, their representatives, the occupational health services, and the radiation protection expert;	The Working Group considers necessary to always involve the RPE in the analysis of this kind of exposure conditions
Art. 59, point 2, letter d)	acceptance testing, involving the medical physics expert, is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any major maintenance procedure.	A specific management system, involving the medical physics expert, is implemented by the undertaking. It includes acceptance tests before the first use of the equipment for clinical purposes, and performance tests thereafter on a regular basis and after any major maintenance procedure	The Working Group considers necessary to always involve the MPE in the management system of medical equipment
Art. 81, point 1, letter a)	occupational health services;	approved medical practitioner/occupational health services;	According to the Working Group, the role of the approved medical practitioner needs to be highlighted, in view of the existing Italian legislation.
Art. 83	Dosimetry services shall determine the internal and external dose to exposed workers subject to individual monitoring in order to record the dose in cooperation with the undertaking and the occupational health service.	Dosimetry services shall cooperate with the RPE and enable the determination of the internal and external dose to exposed workers subject to individual monitoring, in order to record the dose in cooperation with the undertaking and the occupational health service	The Working Group notes that dose evaluation is a specific task of the Qualified Expert, according to the Italian legislation, and dosimetry services offer technical support, and do not evaluate doses.

REFERENCE	COMMISSION'S PROPOSAL	WG PROPOSED VERSION	REASON FOR CHANGE
Art. 84, point 1	The radiation protection expert shall, on the basis of professional judgment, measurements and assessments, give competent advice to the undertaking on matters relating to occupational exposure and public exposure.	The radiation protection expert shall, on the basis of professional judgment, measurements and assessments: a. give competent advice to the undertaking on matters relating to occupational exposure and public exposure. b. assess the dose received and committed by the exposed workers and by the public	As in the definition of the RPE, the Working Group feels that it is needed to stress the role of the RPE in dose evaluation process
Art. 84, point 3	Where appropriate, the task of the radiation protection expert may be carried out by a group of specialists who together have the necessary expertise.	Where appropriate, the task of the radiation protection expert may be carried out by a group of specialists who together have the necessary expertise, and act under the responsibility of the Radiation Protection Expert.	The Working Group wants to stress that, in present Italian legislation in radiation protection, the responsibility for radiation protection tasks clearly remains on the RPE

REFERENCE	COMMISSION'S PROPOSAL	WG PROPOSED VERSION	REASON FOR CHANGE
Art. 86, point 1	Member States shall decide in which practices the designation of a radiation protection officer is necessary to perform radiation protection tasks within an undertaking. Member States shall require undertakings to provide the radiation protection officers with the means necessary for them to carry out their duties. The radiation protection officer shall report directly to the undertaking.	Member States shall decide in which practices the designation of a radiation protection officer is necessary to perform radiation protection tasks within an undertaking. Member States shall require undertakings to provide the radiation protection officers with the means necessary for them to carry out their duties. The radiation protection officer shall act in agreement with the radiation protection expert and report directly to the undertaking.	The Working Group wants to stress that, in present Italian legislation in radiation protection, the responsibility for radiation protection tasks clearly remains on the RPE
Art. 86, point 2, letter m	The task of the radiation protection officer may be carried out by a radiation protection unit established within an undertaking.	[TO DELETE]	The Working Group notes that, in present Italian legislation, the tasks of radiation protection officers are never under the responsibility of the undertaking (as the Qualified Expert is!), but of the employer.
Annex VIII, A, 4, d)	the responsible occupational health service; and	the responsible approved medical practitioner/the responsible occupational health service; and	According to the Working Group, the role of the approved medical practitioner needs to be highlighted, in view of the existing Italian legislation.

Annex 1: Note from AIRM

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Classification of workers exposed to ionizing radiation and medical surveillance

The ICRP's last report, Publication 103 (The 2007 Recommendations of the International Commission on Radiological Protection) states that "…*the LNT model receives considerable, although not decisive, support from epidemiological studies of radiation-related cancer risk, in the sense that the risk of mortality and morbidity from all solid cancers combined in the LSS (Life Span Study) is proportional to radiation dose down to about 100 mGy, below which statistical variation in baseline risk, as well as small and uncontrollable biases, increasingly tend to obscure evidence concerning any radiation-related risk. This uncertainty is the main reason why it is generally impossible to determine, on epidemiological grounds alone, that there is, or is not, an increased risk of cancer associated with radiation exposures of the order of a few tens of mSv and below.*"(ICRP 2007, pag.197-198)

Based on the reports, therefore, it is clear that there is, in scientific assumptions and the resulting application stages, a fundamental inconsistency in differentiating within the range of dose of some mSv and tens of mSv, from a point of view of biological risk and the resulting medical radiation protection standard, workers for whom is expected an effect quantitatively consistent. It is extremely difficult to define, within the range of 1-20 mSv dose, appreciable differences of "detriment" (and therefore risk).

Regarding the inconsistency, it should be highlighted that there is a scientific-doctrinaire aspect that is intimately connected with the concept of biological risk. The individual susceptibility to disease is one of the most obvious evidence gathered by clinical medicine over the centuries; but certainly the most important characteristic of the effects of the exposure to ionizing radiation at low doses, the so called "stochastic

effects", is related to the individual variability. The epidemiological evidence already points out diversified implications between males and females, between subjects of different age or differences, sometimes considerable, in particular incidence of certain cancers between different populations; and this is precisely the reason for ICRP to propose nominal risk coefficients. The Commission's risk estimates are called 'nominal' because they relate to the exposure of a nominal population of females and males with a typical age distribution and are computed averaging over age groups and both genders. As with all estimates derived from epidemiology, the nominal risk coefficients do not apply to specific individuals. The adoption of the multiplicative model by the ICRP takes account of a particular issue related to individual susceptibility: age. Based on the foregoing, therefore, the nominal risk coefficient is, in the assessment on the individual case, a function of various parameters related to oneself, and in particular, to report only those of a more general nature: sex, age at the time of exposure, the belonging population. But alongside these we can not forget the correlations related to the specific hereditary conditions, to particular habits of life, a special working conditions and those connected with special synergistic *noxae (risk factors)*.

This leads to the need to operate, in terms of medical prevention and protection, uniformly on all workers because, in case of exposure to the lowest doses allowed, if differences could be, they should be based on concrete (true) biological characteristics of individuals, rather than on effective doses (within the range of 1-20 mSv).

Therefore, it becomes totally incongruous to admit that the medical surveillance of exposed workers is necessary (and therefore compulsory) only for those workers with greater potential exposure (within the range of 6-20 mSv). This approach would in fact rise to unjustified discrimination because, from an operational point of view, the scientific rigor requires indiscriminately to protect all workers exposed to a risk that is, "*ex ante*", of the same entity.

It is therefore necessary to ensure a uniform standard of prevention and protection to all workers exposed through the performing medical surveillance regardless of the levels of potential exposure and the individual biological variability. This medical surveillance should be entrusted to a medical expert (*expert physician*) (the "approved medical practitioner") whose specific professional capacity is verified through

appropriate mechanisms for recognition by national authorities. ("... Whose capacity to act in that respect is recognized by the competent authorities" - art.1 Dir. EURATOM 96/29)

This figure is thus to ensure the best level of radiation protection in the workplace and protect not only the worker, but also the employer in relation to the obligations that the legislation poses against him.

Based on the foregoing, we ask to:

a) obtain an *equal standard of prevention* indiscriminately *for all workers exposed* to ionizing radiation, as stated by ICRP pubbl.103/2007

b) *protect* the quality of standard medical surveillance, requiring that it *should* be entrusted to a physician for which *have been completed* audits for the recognition of professional skills, as stated in articles. 1 and 38 of EURATOM 96/29 Directive.