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Regulation and enforcement procedures

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INTRODUCTION

Nonionizing radiation is capable of causing effects in biological systems under certain circumstances. Everybody is exposed to various forms of NIR in everyday life, but this alone would not justify the introduction of administrative measures to control the production, distribution and application of NIR sources. Nevertheless, because some of the effects may lead to changes that are potentially hazardous for biological systems, and because of the rapidly expanding use of NIR for telecommunications, as well as for scientific, medical, industrial, commercial and domestic purposes, and the multiplicity of radiation-emitting devices and installations, certain regulations are necessary *(1)*.

A potential hazard to health can be produced either as a result of the exposure of the human body to NIR, or by interaction with technical devices, which are themselves affected by NIR and then give rise to health hazards (e.g. interference with electromedical devices, unintentional triggering of electrically activated detonators, and ignition of flammable materials). This is especially true if the individuals concerned are not aware of the potential hazard or are unable to identify it.

In previous chapters, where the various types of radiation are discussed in detail, guidance is provided on the application of regulatory controls. However, in many cases if such guidance, which is aimed at ensuring the effective protection of both public and individual health, is to be put into practice it will have to be given the force of law. Three successive phases may be identified in the orderly development of regulation and enforcement procedures. First, biological changes and possible hazards to health are identified and studied. Next, based on such studies, standards are derived and proposed. These are generally of two types, namely exposure standards (concerned with individuals who may be exposed either occupationally or in the course of everyday life) and emission standards (concerned with devices and installations which emit NIR, whether intentionally, incidentally or because they have developed a fault). The third phase is the translation of exposure and emission standards into appropriate procedures.

The normal way for a government to introduce legislation in a new technical field is to apply approved and accepted legislative principles to it. In many countries, the basic legislation is supplemented by ordinances and rules designed to meet specific needs. This provides adequate flexibility to permit adaptation to future developments in science and technology.

It must be accepted that the national legal practice of each individual country must take precedence. Thus, general guidance on the application of technical recommendations may often be inappropriate as a basis for making regulations to cover a specific case. For this reason, the intention here is only to give information on the methodological aspects of regulation and enforcement procedures, and to discuss their advantages and disadvantages, irrespective of their compatibility with existing legal traditions.

INTERNATIONAL AGREEMENTS

When legal provisions laying down technical standards, e.g. exposure limits, are introduced, the applications of the particular branch of science or technology concerned are restricted to those existing at the time of enactment. Whether or not those standards can be adapted to meet subsequent developments will depend on the legislative procedure. The consequences may therefore be, firstly, to inhibit the application of further technical developments and, secondly, to establish trade barriers between countries. This may occur even if their safety philosophy and protection policies are essentially the same. A more formal but typical example is provided by national requirements for the marking of certain products or components by means of symbols or colours. The failure of certain devices to comply with the requirements of a national standard can sometimes be due merely to the fact that the labelling requirements of other national standards are different. Uniformity in identification is by all means an essential safety requirement. However, the replacement of, for example, one of the conductors in a finished complete circuit, because it is necessary to change the colour of the covering or insulation to satisfy export requirements, is not only uneconomical but also gives rise to a greater risk of errors. This can easily be avoided by international agreements.

National standards will depend on the state of knowledge at the time of adoption. If the technology is rapidly developing, such national standards are likely to differ if adopted at different times. Unless internationally agreed standards for NIR are adopted in the near future, the piecemeal adoption of national regulations may lead to a situation of this kind.

The preparation of internationally accepted scientific recommendations establishing an international safety level is probably the best way of preventing such a situation from developing. A good example of such recommendations in the field of ionizing radiation are those of the International Commission on Radiological Protection (ICRP) *(2)*.

As early as 1974 it was suggested that an international commission on protection against NIR be formed along the lines of the ICRP *(3)*, but for various reasons such a commission has not yet been launched. However, a valuable initiative was taken by the General Assembly of the International Radiation Protection Association (IRPA) in 1977 in establishing an IRPA committee on NIR. This committee is cooperating with WHO in the preparation of a number of NIR environmental health criteria documents.

TECHNOLOGICAL DEVELOPMENT AND PROTECTION MEASURES

Any radiation protection measures, whether enforced by law or not, that are effectively implemented, limit the possibility of scientifically observing the effects of radiation exposure on the human body. Indeed, the mere suspicion of a hazard is sufficient for protection measures to be taken in order to prevent possible effects. Because of such protection measures, practical experience of effects on man is reduced to the observation of exceptional cases. A particular protection measure will be judged effective if, following its introduction, cases of radiation damage are rare. As a consequence, the necessary experience can be obtained only over long periods of time or from animal experiments correlated with observations on man. Such results will require careful interpretation.

Legislation should be introduced to require the reporting to a central registry of radiation accidents or incidents involving abnormal exposures. Evaluation of such reports can provide valuable insight into potential problem areas requiring regulatory control. It is necessary, however, to avoid drawing inappropriate conclusions with regard to cause and effect and radiation risks. Such conclusions are valid only if they are supported by systematic experimental and epidemiological research.

Moreover, legislation should avoid the possibility of hazards resulting from the use of a particular type of radiation and from the frequency and duration of this application. The necessary data should be obtained by whatever means may be most effective and appropriate. This may involve a survey of those cases where the introduction of protective measures has proved necessary.

Many countries have general regulations covering the safe application of new technologies. Based on such regulations, protection measures could be introduced at an early stage. Unfortunately, such cases are the exception since the control of all technical developments, before the existence of any potential hazard has been confirmed, is very expensive and time consuming and often not in harmony with existing political principles. Yet, for most of the applications of NIR, technical developments are so far advanced that the necessary protection measures are already embodied (or will be in the near future) in special regulations for the type of radiation concerned. In this connection, reference may be made to the legislation on protection against NIR which already exists in a number of countries.

DATA FOR LEGISLATION

As mentioned previously, there is a risk that rapid technical development will result in a gap between the present state of technology and existing regulations, since the translation of advanced knowledge into adequate legal controls always requires a considerable period of time. Introduction of regulatory controls when technical development has reached an advanced stage is a poor alternative. From experience with air and water pollution control in large industrial centres, it has been learned, for example, that it becomes rather difficult to introduce more stringent protection measures without hurting already existing industries.

Only in the last few years has it been realized that the development of new technologies should go hand in hand with systematic research on potential health hazards and the introduction of adequate protection measures. One step in the right direction is substantial governmental support to appropriate fundamental investigations to meet the most urgent needs. This support should complement the resources already allocated by industry and public funding for improving the design of technical equipment and installations which are or include NIR sources. Great efforts will be necessary if a dangerous increase in the gap between the state of technological development and the available protection measures is to be avoided.

Although scientific publications on the causes of NIR effects or on the development of protection measures are based on systematic research, no fundamental general strategy exists for the generation of adequate scientific information necessary for the drafting of legal provisions on radiation protection.

The general objective is to use NIR for the benefit of mankind while avoiding potentially harmful effects on health and the environment. Even the first step towards this objective, however, leads to a quantitative problem. Not every biological effect caused by NIR is harmful. The question therefore arises of limits for radiation exposure below which no harmful effects will be produced in the exposed individual or group. Knowledge of such limits is thus essential in order to ensure, by means of legislation, that they are not exceeded. A review of the relevant literature for each type of radiation does not always reveal agreed numerical values for these limits.

The establishment of exposure limits and acceptable regulatory procedures for the safe use of NIR poses a number of problems. Not only are there deficiencies in the scientific literature, as already noted, but the limits of validity and accuracy of the scientific data presented must also be recognized. Furthermore, it may be necessary to take action even though a causal relationship has not been established. Consequently, and despite such deficiencies, an effort must be made to assess the relative hazards from NIR with regard both to the severity of the harm resulting from a particular operation and to its risk (i.e. the probability that such harm will occur). That probability must also be related to the population exposed, which may be either an occupational group or the general public. The information thus obtained will provide the scientific basis for the establishment of legislation and/or appropriate regulatory procedures. Where serious hazards are involved the legislator may require an assessment with respect to their severity and risk.

STANDARDS

The philosophy and principles underlying the development of exposure and emission standards for ionizing radiation protection have been thoroughly treated by ICRP. Essentially, the aim has been to develop exposure guidelines, i.e. basic and derived limits for human exposure to ionizing radiation.

Similar approaches may be appropriate in the development of standards for NIR protection. However, because present knowledge of the fundamental mechanisms of NIR interaction and the associated biological effects is still less developed, and because it is not known in all cases whether stochastic as well as non-stochastic effects will occur, existing protection measures must be regarded as provisional. In addition, it is still not certain whether the mechanism for the transmission and expression of hereditary traits is affected. In cases of uncertainty, protection measures should err in the direction of providing greater safety. In this case, the philosophy adopted by ICRP *(4)*, namely the ALARA (as low as readily achievable) principle, might provide an interim and conservative basis for a standard until more quantitative data on biological effects become available.

The setting of emission or exposure standards implies the ability to measure the particular type of NIR concerned. To obtain valid and compatible measurements, it is necessary to ensure that measuring equipment is properly calibrated and recalibrated by means of specified techniques, and that the measurement procedures followed are in accordance with those prescribed.

Exposure standards

Exposure standards may include basic limits and derived limits, as set out in ICRP Publication 26 *(2)*. When the purpose of establishing limits is public health protection, it would be appropriate to refer to them as limits of permissible exposure rather than safety levels. Although the concept of permissible exposure is designed to limit risk, it may not ensure absolute safety because of the lack of definite information on the biological effects of chronic or repeated low-level exposure to NIR. Protection limits may be set both for those who are occupationally exposed and for the general population.

Emission standards

Emission standards are protection standards designed to limit the risk from products or devices that may emit NIR hazardous to human health. They will also limit leakage of radiation, where this is incidental to the primary functions of the product or device. Such standards may require the incorporation of safety features designed to prevent or minimize human exposure to radiation (e.g. screens and interlocking devices).

Regulation and enforcement procedures

These represent the translation of exposure and emission standards into the control system of a country. They will vary according to the magnitude and the probability of the hazard to health, and the details will depend on the legislative practices of the country. Some such common procedures, arranged in descending order of stringency, include the following.

Licensing of installations or devices. This type of procedure requires that facilities and institutions using NIR devices be licensed and comply with the appropriate standards, including exposure and emission standards, in order to retain their licensed status. This may include the designation of controlled areas around installations. Access to such areas may be restricted and, in certain circumstances, residence in them may be prohibited.

Statutory regulations. These are mandatory rules having the force of law which require compliance by the user; it is the user's duty to know the law and to obey it. The regulations are generally based on accepted exposure and emission standards. The user is required to provide equipment and to make contingency plans for dealing with accidents and emergencies.

Registration. It is sometimes the case that the introduction of a hazardous technology or process may have to be notified to and registered by the enforcing authority, which may then grant permission for its use.

Notification. This is a less stringent requirement and does not include the granting of permission for use.

Voluntary procedures. These may be applied to both exposure and emission standards; the former may be embodied in codes of practice, while the latter may be developed by industry by consensus, with self-monitoring. Should a risk to human health be identified as a result of the violation of the voluntary standards, or should a clear danger to human health be associated with radiation emitted by a product not covered by a standard, action can be taken under a "defective product procedure". Such a defective product would be identified as one emitting radiation at intensities of such magnitude as to constitute a hazard to human health. The responsibility for demonstrating that the product was not defective would lie with the manufacturer, who would also be responsible for taking the necessary corrective action.

Guidelines and recommendations. These represent a voluntary approach to radiation protection. Guidelines and recommendations may cover equipment, procedures, facilities and the conduct of physical and medical examinations.

Quality assurance programmes. Such programmes are designed to encourage practices among manufacturers and users of radiation-emitting products and devices that will effectively reduce exposure and/or any risk that may be associated with the use of the product or device.

Certification. Certification of professionals and technicians can serve to ensure that only individuals with appropriate training are permitted to operate or service equipment that may be potentially hazardous.

Education and training

Education and training programmes serve to teach professionals, technicians and members of the general public about the risks that may be associated with exposure to NIR. Through education, users at all levels may better appreciate the risks to which they may be exposed, and therefore be amenable to taking those steps that may be effective in limiting risk, such as reduction of exposure for diagnostic examinations, avoidance of routine exposure, and use of equipment in conformity with safety recommendations.

SAFE EXPOSURE LIMITS

Many devices emitting NIR are already being produced in large quantities by modern industrial methods. The question thus arises once again as to which devices can be regarded as safe, even if this decision has to be taken in the absence of a complete knowledge of the biological hazards. A few relevant concepts are presented in what follows, with the object of stimulating the development of appropriate strategies from which existing legal practices can be derived for special cases.

For the purposes of these more fundamental considerations, it is assumed that the relation between cause and effect has been investigated sufficiently to enable a hazard limit to be defined. The difficulties involved in defining such a limit are discussed below to demonstrate the resulting consequences.

Causal model

The irradiation of a biological system, e.g. a human body, is shown diagrammatically in Fig. 1A. Increasing irradiation is shown by the direction of the arrow on the abscissa, on which the level of irradiation which causes injuries to living tissue can be plotted, and is considered to be the hazard limit. It is not an absolute limit but represents the most probable value above which irradiation may cause biological damage. Because of variations in biological response, there must always be some degree of uncertainty as to the actual value of the hazard limit.

A safe exposure limit, i.e. one about which there is no uncertainty — and this is a requirement that has often to be satisfied before such a limit can be incorporated in legislation — must by definition be lower than the lowest value for which any uncertainty does exist. Because scientific knowledge is incomplete, it will also be necessary to include a safety factor. The difference between the safe exposure limit and the level of irradiation at which damage is most likely to occur indirectly indicates the state of scientific knowledge.

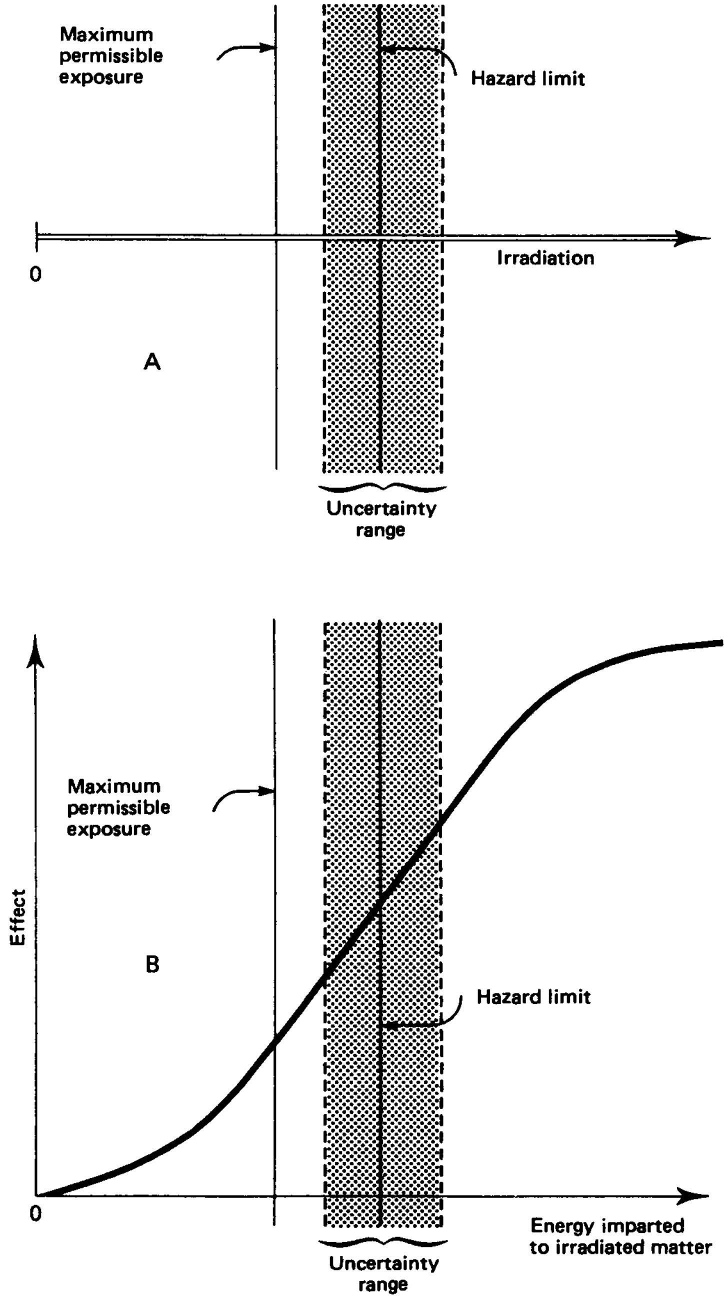
The diagram can be completed by plotting on the ordinate the severity of the biological effect produced by irradiation (Fig. 1B). This is done on the assumption that a true causal relationship exists between irradiation and effect.

In a first approach, it is assumed that low exposures do not cause a measurable effect. With increasing irradiation, however, the effect also increases, at first slowly and then more rapidly, up to a level above which the effect cannot be increased by more intense irradiation. This level is reached when all life functions of the biological system have been destroyed. Thus, a sigmoid curve is obtained under these circumstances, the assumed hazard limit being located at a certain point on the curve (Fig. 1B). Irradiation above this level is considered to constitute a health hazard.

If one disregards the important question of whether this simplification of the relationship is admissible for each type of NIR, the fixing of a hazard limit and thus of an exposure limit is in any case significant only if what is meant by a harmful effect has been clearly defined. This problem cannot be solved without discussing which physiological or biological parameter is to be used as a measure of the effect and which physical parameter as a measure of irradiation. It must be remembered that Fig. 1 is only a model but, with all its uncertainties, it does demonstrate the fundamental problems involved in the assessment of exposure limits, independently of the true relationship between response and irradiation.

The definition of the effect constituting the hazard is of the utmost importance; it is because of the lack of a clear and uniform definition that many of the data given in the literature are not comparable. For example, the WHO Constitution itself gives a definition of health which may not

Fig. 1. Irradiation of a biological system



Note. A = a simplified model; B = a model with allowance for the severity of the biological effect.

always be appropriate to quantitative scientific research. According to this definition, health is a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity. In the light of this definition, different values for a hazard limit can be obtained depending upon whether it is intended merely that disease is to be avoided or whether wellbeing has to be ensured. There is no doubt, however, that both kinds of definition are justifiable. This can be seen, for example, in the case of certain microwave standards, where the level for uncontrolled exposure is so low that no adverse effect on wellbeing is to be expected, whereas under well controlled working conditions, higher exposure levels are permitted for a certain period of time. Thus the replacement of conventional sources of heat by microwave devices in industrial processes, e.g. in the drying of foodstuffs, may improve working conditions considerably, even if the wellbeing of the workers is marred by a certain residual discomfort.

In the model shown in Fig. 1B, a value is postulated for the ordinate which can be determined objectively and which is causally related to the irradiation. It is also possible to quantify the effect in terms of subjective reactions, but a statistical survey is then necessary in order to eliminate the effect of other factors that can produce similar effects (e.g. headache, fatigue).

As far as irradiation is concerned, it would be desirable for a physical quantity to be selected which is correlated as closely as possible with the effect observed. Some other secondary physical quantities may sometimes be more suitable from the point of view of normal routine assessment, but will be acceptable only if a clear-cut relationship exists between the secondary and the primary physical quantities. If this relationship is not fully understood but the secondary physical quantity is one that is indispensable for practical purposes, a relationship can initially be postulated. Corrections can then be made subsequently as valid data become available as a result of further research.

For the abscissa in Fig. 1B, a physical quantity is preferred because both the physical properties of the various types of radiation and the measurement techniques are well known. It is thus possible to draw up the necessary quantitative specification, and a high degree of reproducibility of the data can thus be ensured.

The physical quantity often preferred is the energy imparted to matter, since this is of fundamental significance in almost all kinds of effect. Only under certain conditions, when a mechanism exists whereby the energy can be dissipated out of the irradiated body region, would the corresponding quantity be the power. This implies an equilibrium between energy input and output. An example is the production of heat by the interaction of microwave radiation with tissue and the dissipation of this heat to non-irradiated body regions. Instead of the energy or power, the corresponding specific values, referring to mass, volume or surface, will be preferred if independence from the irradiation geometry is important.

Although an appropriate choice of a physical quantity as a measure of irradiation would seem an obvious requirement, many reports on the relationship between cause and effect have been published in which the data have been expressed in terms of other quantities more easily measured under experimental conditions. If the authors then neglect to specify the relationship between the data obtained and any precisely defined fundamental quantity, or if the paper provides insufficient information to permit the necessary relationship to be derived from the experimental conditions, the value of the research, for purposes of comparison or the assessment of hazard limits, is reduced. Even if important observations are made regarding the general problem of evaluating potential health hazards, failure to indicate the reference quantity for the irradiation of an object may limit the significance of otherwise excellent investigations.

An effect which changes significantly in magnitude when the intensity of the irradiation is changed would be suitable for use in experiments and can thus easily be observed. If possible, there should be a clear-cut relationship between effect and irradiation. In the selection of a parameter which is a measure of the hazard to the irradiated biological system, the effect to be observed must be related to its life functions. Finally, if the investigations are not carried out on man, extrapolation of the results to man must be feasible. This requirement may seriously limit the effects which can be considered, but must be satisfied if a valid model is to be obtained.

As already pointed out, the biological response mechanism, postulated in the model shown in Fig. 1B, starts with a threshold level for the irradiation below which no effect is observable. Above a certain level of irradiation, further increase does not produce an increased effect. A sigmoid curve for the relationship between effect and energy imparted to matter would thus be expected. Whatever the mechanism underlying the model, the threshold level might be very low, and possibly even so low as not to be observable. The curve would then pass through the origin.

The model will not correctly represent the situation if the wrong reference quantity has been chosen, e.g. the temperature of the body is a closely temperature-regulated physiological system, as in human beings. A threshold level would then be simulated, although there would definitely be other effects, such as stimulation of the entire metabolism, without a rise in body temperature. A rise in temperature would already be a danger sign and the rise could continue even if the individual were already dead. However, if a cell population was involved, the model would be satisfactory if the number of dead cells were counted. Below the threshold level all the cells would survive the irradiation. The death rate would then rise until all the cells had been killed. A further intensification of the irradiation could not increase the effect.

If it is assumed that a clear-cut cause–effect relationship exists, these examples demonstrate that the relationship between the dose–effect curve and the ordinate and abscissa is determined by the choice of parameters for observation.

Phenomenological model

Because of the multiplicity of observable parameters of radiation effects, a more pragmatic approach is, in general, unavoidable. Procedures will therefore initially be based on observable phenomena. For each parameter it will be necessary to investigate which phenomenon occurs when the irradiation level is increased. In this phase, no attempt need be made in the investigation to explain the observed phenomenon or to determine the relationship between the changes in different parameters and the radiation level.

These methods, although they are well accepted and scientifically valid, should be used with caution in the determination of hazard limits or exposure limits. It is necessary to ensure that, in the course of the investigation, all the parameters relevant to the hazard concerned have been examined. Among the numerous phenomena there may be effects that are of no importance from the point of view of defining a hazard limit. This is the case if health or life functions are not adversely affected. It would also be inappropriate to use a particular effect for the determination of hazard limits if a different effect occurs at lower irradiation levels.

The objective of defining radiation hazard limits can be achieved only if a well thought out strategy exists. If parameters are examined at random, an important parameter may well be overlooked.

The phenomenological approach, i.e. the observation of effects occurring during or after radiation exposures but without the construction of a hypothesis as to the response mechanism, is often the only possibility in view of the extreme complexity of the physiological reactions involved. However, there is always the danger than an apparent correlation between cause and effect may be found that does not really exist. This will lead to serious errors if conclusions are subsequently drawn from such a correlation.[a]

Thus changes in the skin, such as the repeated development of erythema following time-correlated successive occupational exposure, establishes a cause–effect relationship, although similar skin changes may occur, for example, after exposure to the sun. The causal relationship often cannot be established with certainty if the parameter selected is an ill effect which becomes apparent after a fairly long latency period and if this ill effect may be caused by other factors. In this case, only long-term, large-scale surveys can help in detecting quantitative relationships which are statistically valid and significant. The scientifically important statement that a particular type of radiation in sufficient quantity can cause ill effects is not sufficient to define quantitatively the hazard limit.

The above discussion, though brief, shows that the objective of a research strategy for obtaining scientifically based data for determining the permissible exposure and the exposures to be prohibited, should be to investigate effects unequivocally caused by the radiation concerned. Sound decisions can then be made as to the requirements that may be imposed by law.

Conservative assumptions

Since the scientifically based dose–effect data for most of the NIR are still fragmentary, and therefore not yet suitable for regulation purposes, other

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[a] A good example is the statistically significant correlation between the decline in the birth rate in certain countries and the decrease in the number of storks. This does not, however, prove that babies are brought by storks, as children used to be told.

methods for limiting radiation hazards must be found. It is sometimes helpful to define a maximum permissible exposure which is lower than the lowest of all expected threshold levels for radiation hazards (Fig. 1B). Where the relationship between irradiation and effect is unknown, the most favourable case is assumed, and a safety factor is used (in the model, this is the distance between the hazard limit and the maximum permissible exposure). If, subsequently, as a result of systematic investigations, a more refined approach becomes feasible, the exposure limit can be modified.

However, the foregoing method may sometimes be inappropriate. If the basic data are uncertain, this type of assessment can lead to exposure limits which are too low for practical application, and a different approach must be adopted. If special protective measures are prescribed for sensitive organs or parts of the body, higher exposure limits may be acceptable.

Where specific reactions develop in organs or parts of the body after irradiation, the exposure limits are often determined by the effects on such "critical organs". An example of such an organ, in relation to the visible spectral region, is the eye, and especially the retina, as far as laser beams are concerned. If protection of the critical organ is possible, consideration can be given to relaxing the exposure limit. In the foregoing example, the eye can be protected from irradiation by enclosing the beam or by providing protective glasses.

It is sometimes sufficient to avoid exposure only during certain periods. For instance, if a particular radiation danger exists for the fetus, occupational exposure of pregnant women should be discouraged or, if necessary, access to certain areas should be restricted for women of reproductive capability. Many examples of restrictions of this kind are found in occupational hygiene. All of them show that restrictions have to be adapted to each specific situation and that their observance must be controlled. Thus, the critical analysis of existing scientific data leads to the requirement that legally supported regulatory and enforcement procedures must be introduced, though this is certainly not the only reason for doing so.

COMPLIANCE AND ENFORCEMENT

The success of any proposed regulation and enforcement procedure will depend finally on whether it can be applied in practice. There are cases where well established procedures break down simply because the institutions responsible for their enforcement are overloaded with work, the resources inadequate or the necessary experts not available. The administrative and economic limits are quickly reached when the applications concerning devices, installations or radiation sources are so numerous as to exceed the ability to control them. Moreover, resources are not being effectively used when they are allocated to the surveillance of applications involving a small degree of risk, while more hazardous applications remain uncontrolled.

In order to achieve the aims of protection, it is advisable that the enforcement procedures for the proposed regulations be critically reviewed in advance. Enforcement is subject not only to legal provisions but also to technological and administrative measures. It is also important to understand that legislation is more likely to be effective if it has the support of public opinion. This may be achieved by informing and educating the public, or at least those directly affected by the legislation. The feasibility of legislation is generally predetermined by the political and administrative structure and the technical and professional organizations available to support enforcement of the proposed provisions. Because of the correlation between enforceable legal provisions and technical requirements which are in accordance with the state of science and technology, certain other generally applicable regulatory methods may be considered.

Approval of application

Approval of application implies that neither the device nor the installation but rather the user is subject to regulatory procedures. The requirements for authorization should be carefull defined. The provisions for authorization should include the requirement for an official examination of the installation by a professionally competent person.

Where authorization is required, prior approval of the installation containing the NIR equipment should also be obtained. The complete procedure is time-consuming and can be recommended only if there is a significant risk to the environment, to the public, or to persons exposed to radiation in the course of their work. This procedure is not only effective from the point of view of health and safety but can be of advantage to the applicant, because he can calculate the cost of the necessary protective measures before he begins operation. Thus, the investment required can be assessed at the planning stage.

It is also possible to apply this procedure in stages. Hence, the plans for the installation and the necessary devices can be approved separately before the installation is constructed, and operation will then be authorized after the protection measures have been finally accepted as adequate. Thus, the considerable financial risk involved in the construction of large installations, such as failure to obtain authorization after construction has been completed, can be reduced. A typical example is high-power radar air traffic control equipment located near a city, which may affect residential areas in the vicinity, and possibly also life-saving electronic equipment in nearby hospitals.

Moreover, it is appropriate to introduce regulatory controls covering the use or operation of NIR equipment, even if the extent of such use is insufficient to warrant a system of prior approval. However, the requirements to be satisfied by the user or operator should be clearly set out, and should specify the objectives to be achieved. Prior notification of use may also be required.

Regulatory control with or without prior notification allows the user to commence operation without waiting for any action on the part of the regulatory authority. Provided the user meets the requirements laid down, he is secure in the knowledge that he will not subsequently be required to introduce additional protection measures or to suspend operations. However, the user lacking in expertise will often find it necessary to seek assurances from the regulatory authority or from some other advisory body that he has interpreted the requirements correctly and is applying them appropriately.

Approval of equipment

The approval procedure can be simplified if it is possible to fit safety devices to the radiation source, which either completely prevent any exposure or reduce it to a prescribed level. If protection can be ensured by construction and design, the equipment itself will satisfy the regulatory requirements. The technical performance necessary, safety requirements, information and labelling also need to be specified. The performance will, in many cases, be specified in terms of an exposure limit, measured under certain prescribed conditions. Such exposure limits differ fundamentally from permissible exposure limits for individuals, in so far as they are derived limits fixed in such a way as to ensure that the permissible exposure limits for individuals are not exceeded under any conditions of use. It is therefore advisable to give such an exposure limit a different name, such as emission limit. In specifying values for emission limits, account should be taken of such aspects of protection as the possibility of operational breakdown as a consequence of defects which cannot be totally excluded by technical means.

If acceptable emission limits cannot be achieved by suitable design measures, additional protection measures will then be necessary, such as the provision of additional shielding, restriction of access and/or the introduction of administrative controls.

The mass production of devices calls for other methods in order to simplify the regulatory procedure. One possibility would be to test a prototype of the device and require the manufacturer to ensure that each device produced was in conformity with that prototype. It must be pointed out that this procedure can be limited to the production process only if the equipment was designed with adequate protective devices, and can be used according to the specifications without any additional protective devices. It is also necessary to ensure that exposure cannot exceed the maximum permissible level for members of the general public. Inspection is thus reduced to the surveillance of a small number of manufacturers instead of a large number of applicants. The reliability of the manufacturers and the technical safety of the equipment will determine whether each individual product will need to be inspected for conformity with the prototype, or whether the testing of random samples will be sufficient.

Remedial protection measures

All the procedures previously described are preventive in character. They are intended to reduce the extent of potential hazards to a certain known and acceptable level or to avoid them completely. Another procedure that will reduce the need for administrative controls would prescribe, in technical standards, either the design and properties of the device or the maximum permissible radiation emission. Legislative measures would follow only if there was reason to believe that these standards had not been complied with during the production process. This procedure is particularly effective when devices are produced in large quantities by different manufacturers. If it becomes generally known that the products of any particular manufacturer are unsafe, his economic position will be jeopardized. As a result, this system is self-regulating.

Inspection and maintenance

One of the main problems in radiation protection is to ensure that equipment remains safe after it has been in use for a long period. If the equipment or installation is subject to regulation, the regulatory administration or the officially authorized institutions must be empowered to confirm, either periodically or by means of random checks, that the requirements are still being complied with. If responsibility has been assigned to the manufacturer, however, further provisions will be necessary to ensure that the safety devices remain effective after delivery of the equipment to the user. Periodic checking and maintenance visits must take place, if necessary. It is also important to ensure that repairs are carried out by qualified personnel, so that protection measures are not impaired as a result of such repairs.

Review of regulations

The rapid technological developments in the field of NIR, together with the increased understanding of its bioeffects, are likely to lead to changes in exposure and emission standards. It may, therefore, be prudent for the regulations based on those standards to remain in force only for a limited period of time so as to provide an opportunity for review in the light of new knowledge.

Changes in the standards and in the regulations based on them may make certain types of equipment unacceptable to the regulatory authority. Therefore, subject always to the overriding considerations of health and safety, consideration may also be given to the gradual introduction of revised regulations. This would enable a reasonable period of time to be allowed for alterations and adjustments to be made to existing equipment.

Exemptions

An effective method of rationalizing the regulation and enforcement procedures is the introduction of exemptions for particular applications, namely, those which are considered to be harmless. Any such exemption limit can be withdrawn if necessary, e.g. for devices which are widely used or which can be used for purposes other than those for which they have initially been designed.

Information programmes

No system of controls depending on regulatory and administrative procedures can be made completely safe if a user is determined to ignore or to circumvent the safety measures designed to protect against potentially hazardous NIR. It is therefore essential that information and education programmes be introduced to complement and supplement other aspects of the control programme. A comprehensive and effective programme of information and/or education for users at all levels should alert them to the potential hazards of exposure to NIR, heighten their awareness of the need to avoid unnecessary exposure, and promote respect for any instructions, recommendations and guidelines that may be issued for the purpose of promoting safe practices.

Situations may indeed exist where recommendations and guidelines, effectively developed and publicized, may constitute the entire programme necessary to ensure the protection of public health and safety. The potential adequacy of such an approach to protection should be explored in any case where it may be applicable.

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GLOSSARY[a]

As in most relatively new fields, the terminology used in studies of the health effects of NIR is in many respects confused. With the exception of physical quantities — for most of which standardized names have existed for many years — there is little international standardization of NIR terminology. In some cases, different authors use a given term with different meanings, while in others they use different terms with the same meaning. Even in the few areas for which internationally agreed, standardized terminology exists, many authors do not follow the recommendations.

An attempt is now being made to achieve agreement on terminology for the more important health-related aspects of NIR. Pending the outcome of that effort, the short glossary that follows is included in this publication in order to draw attention to those terms that have already been standardized internationally. Most of these terms are the names of physical quantities, and in such cases the recommended symbol(s) and units of measurement are included. The expression "reserve symbol" refers to a symbol that, while not recommended, may be used (to avoid confusion) in any context in which the preferred symbol is used for some other purpose. The sources of the recommendations are listed at the end of the glossary.

absorptance, spectral See *absorption factor, spectral*

absorption coefficient, linear The part of the linear attenuation coefficient that is due to absorption. (ISO, *4*) Symbol, a; Unit, reciprocal metre, m^{-1} *See attenuation coefficient, linear*

absorption factor A weighted average of the spectral absorption factor. Symbol, α; Unit, 1 (dimensionless, a ratio)

absorption factor, spectral Ratio of the spectral concentration of radiant or luminous flux absorbed to that of the incident radiation. (ISO, *4*) Symbol, $\alpha(\lambda)$; Unit, 1 (dimensionless); Synonym, *spectral absorptance*

attenuation coefficient, linear The relative decrease in spectral concentration of the radiant or luminous flux of a collimated beam of electromagnetic radiation during traversal of an infinitesimal layer of a medium, divided by the length traversed. (ISO, *4*) Symbol, μ; Unit, reciprocal metre, m^{-1}; Synonym, *linear extinction coefficient*

concentration of radiant energy density, spectral See *radiant energy density, spectral*

emissivity Ratio of *radiant exitance* of a thermal radiator to that of a full radiator (black body) at the same temperature. (ISO, *4*) Symbol, ε; Unit, 1 (dimensionless)

energy surface density See *radiant exposure*

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[a] Compiled for the first edition by Mr D.A. Lowe, Chief, Technical Terminology Service, World Health Organization, Geneva, Switzerland.

exposure See *radiant exposure*

extinction coefficient, linear See *attenuation coefficient, linear*

impedance, acoustic At a surface, the complex representation of sound pressure divided by the complex representation of volume flow rate. (ISO, *5*) Symbol, Z_a; Unit, pascal second per metre cubed, Pa• s/m^3

impedance, specific acoustic At a surface, the complex representation of sound pressure divided by the complex representation of particle velocity. (ISO, *5*) Symbol, Z_s; Unit, pascal second per metre, Pa• s/m

impedance of a medium, characteristic At a point in a medium and for a plane progressive wave, the complex representation of sound pressure divided by the complex representation of particle velocity. (ISO, *5*) Symbol, Z_c; Unit, pascal second per metre, Pa• s/m

irradiance At a point of a surface, the radiant energy flux incident on an element of the surface, divided by the area of that element. (ISO, *4*) Symbol, E; Reserve symbol, E_e; Unit, watt per square metre, W/m^2; Deprecated synonym, *power surface density*

phantom A volume of material behaving in essentially the same manner as tissue, with respect to absorption and scattering of the radiation in question. (IEC, *2*)

power surface density See *irradiance*

radiant emittance See *radiant exitance*

radiant energy Energy emitted, transferred, or received as radiation. (ISO, *4*) Symbol, Q or W; Reserve symbols, U, Q_e; Unit, joule, J

radiant energy density Radiant energy in an element of volume, divided by that element. (ISO, *4*) Symbol, w; Reserve symbol, u; Unit, joule per cubic metre, J/m^3

radiant energy density, spectral The radiant energy density in an infinitesimal wavelength interval, divided by the range of that interval. (ISO, *4*) Symbol, w_λ; Unit, joule per metre to the fourth power, J/m^4; Synonym, *spectral concentration of radiant energy density*

radiant energy fluence rate At a given point in space, the radiant energy flux incident on a small sphere, divided by the cross-sectional area of that sphere. (ISO, *4*) Symbol, φ or ψ; Unit, watt per square metre, W/m^2; Synonym not recommended, *radiant flux density*

radiant energy flux Power emitted, transferred, or received as radiation. (ISO, *4*) Symbol, P or Φ; Reserve symbol, Φ_e; Unit, watt, W; Synonym, *radiant power*; Synonym not recommended, *radiant flux*

radiant exitance At a point of a surface, the radiant energy flux leaving an element of the surface, divided by the area of that element. (ISO, *4*) Symbol, M; Reserve symbol, M_e; Unit, watt per square metre, W/m^2

radiant exposure Radiant energy incident on a surface divided by the area of the surface. Symbol, H; Unit, joule per square metre, J/m^2; Synonym, *exposure* (in part); Deprecated synonym, *energy surface density* (*Note.* The term "exposure" has many different meanings, depending on context.)

radiant flux See *radiant energy flux*

radiant flux density See *radiant energy fluence rate*

radiant intensity In a given direction from a source, the *radiant energy flux* leaving the source, or an element of the source, in an element of solid angle containing the given direction, divided by that element of solid angle. (ISO, *4*) Symbol, I; Reserve symbol, I_e; Unit, watt per steradian, W/sr

radiant power See *radiant energy flux*

reflectance See *reflection factor*

reflectance, spectral See *reflection factor, spectral*

reflection factor A weighted average of the spectral reflection factor. Symbol, ρ; Unit, 1 (dimensionless, a ratio); Synonym, *reflectance*; Deprecated synonym, *reflectivity*

reflection factor, spectral Ratio of the spectral concentration of radiant or luminous flux reflected to that of the incident radiation. (ISO, *4*) Symbol, $\rho(\lambda)$; Unit, 1 (dimensionless); Synonym, *spectral reflectance*

reflectivity See *reflection factor*

threshold (*Note.* This term should not be used without qualification.)

threshold, stimulus Minimum value of a sensory stimulus needed to give rise to a sensation. (ISO, *6*) Synonym, *detection threshold*

threshold limit value A concentration (in air) of a material, or a level of noise or radiation, to which most workers can be exposed daily without adverse effect. Threshold limit values, established by the American Conference of Governmental Industrial Hygienists, are time-weighted values for a 7- or 8-hour workday and 40-hour workweek. In most cases exposures exceeding the limit are permissible provided there are equivalent compensatory exposures below the limit during the workday (or in some cases the week). For a few materials the limit is given as a maximum permissible concentration. (After *1*)

transmission factor A weighted average of the spectral transmission factor. Symbol, τ; Unit, 1 (dimensionless, a ratio); Synonym, *transmittance*

transmission factor, spectral Ratio of the spectral concentration of radiant or luminous flux transmitted to that of the incident radiation. (ISO, *4*) Symbol, $\tau(\lambda)$; Unit, 1 (dimensionless); Synonym, *spectral transmittance*

transmittance See *transmission factor*

transmittance, spectral See *transmission factor, spectral*

Sources

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