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Subject A legal analysis of the use of ionising radiation in medical hospital practice: an inquiry into the influence of prevention and precaution on health protection and liability.

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Date January 14, 2004

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Abstract

From a legal perspective there exists a clear need for a general framework describing conditions and consequences of risk management in the field of high technology.

Despite the existence of many kinds of Safety Procedures and Soft Law, specific guidelines are lacking for regulators and courts, especially in case of scientific controversy and uncertainty about the health effects of an activity or a product such as low doses of ionising radiation, electro-magnetic fields, genetically modified organisms, PCB's in salmon etc.

The research of the PISA Project on Legal Aspects and Liability has been focussed on the medical applications of ionising radiation. The safety approach depends on the risk characterisation and differs for stochastic and deterministic effects. The most important objective was to find liability or funding systems which can cope with these differences, in particular between dose limits (as for the nuclear industry), reference dose levels foreseen in the EC medical Directive (as for nuclear medicine), and Optimisation referring to the ALARA principle.

Risk assessment and risk management that are based on traditional narrow risk-assessment models have to be revised in the light of the Precautionary Principle. This principle urges policy-makers to adopt a broader, more pluralistic approach, considering the societal equilibrium, i.e. the general interest of the activity at stake, the general impact of individual protective measures and the existence of "reasonable" alternatives from a sociological, economical, scientific and technological point of view. One of the characteristics of the Precautionary Principle relates to our opinion to the "collective" damage to human health, i.e. a detriment that relates to a group of people.

Nevertheless, as a result of the application of the Precautionary Principle, we believe that in case of individual damage the standard of care shall be more and more defined, following the risk characterisation and assessment which has to be introduced once a scientific or societal problem occurs with regard to medical practices, already subject to the legal duty of Justification and of Informed Consent.

For some specific cases, as paediatric CT doses, the 2003 report of the Belgian Health Council gives a clear warning and refers to collective doses that are significantly higher than in the neighbouring countries. It cannot be denied that such a repeated warning urges decision makers and hospitals to take corrective actions, in particular when poor optimisation is put in place.

Causality in the nuclear field is another complex problem, where worldwide alternatives are under consideration, such as "probability of causation". However, such a concept, based on statistical proof, can hardly be implemented in Belgian law since our tort- and insurance-system is based on the individual relationship between liable actor and victim.