COMMISSION OF THE EUROPEAN COMMUNITIES

COM(79) 158 final

Brussels, 30 March 1979

PROPOSAL FOR A COUNCIL DECISION

adopting a five-year research and training programme

(1980-1984) of the European Atomic Energy Community

in the field of biology – health protection

(Radiation Protection Programme)

(submitted to the Council by the Commission)

COM(79) 158 final

CONTENTS

Summary

The present proposal for an extension of the Commission's Radiation Protection Programme is submitted pursuant to article 7 of the EAEC Treaty. It is proposed as a rolling programme and covers the period from 1.1.1980 to 31.12.1984. Scientific and administrative reasons have guided the Commission to propose such a rolling programme to take rapid advantage of recent progress in radiation protection research and of the changing requirements for radiation protection in the Community, and furthermore to facilitate the management of the programme. The year 1980 is the last of the present programme (1976-1980) and would thus become the first year of the new programme.

The Programme is designed to gain adequate understanding and control of radiation risks with two main objectives:

- improvement of scientific and technical knowledge with a view to updating basic standards for the health protection of the general public and workers against the hazards arising from ionizing radiation ;
- evaluation of the biological and ecological consequences of nuclear activities and of the use of nuclear energy and ionizing radiation, in order to ensure an adequate protection of man and of the environment whenever unacceptable harm could otherwise be caused to them.

The Programme will consist of six major closely integrated activities or sectors which - arbitrarily but conveniently - serve to indicate its overall structure:

- radiation dosimetry and its interpretation,
- behaviour and control of radionuclides in the environment,
- short-term somatic effects of ionizing radiation,
- late somatic effects of ionizing radiation,
- genetic effects of ionizing radiation,
- evaluation of radiation risks.

The implementation of past programmes has shown that its execution in research contracts with National Institutions and Universities ("indirect action") combined with an efficient management with the help of the ACPM and based on objective procedures for evaluation are the appropriate means for the

execution of this Community research programme. Improvements to the mechanism by which the programme is managed are constantly sought and implemented as appropriate. In general it keeps the administrative charge for contractors and scientists as low as reasonably achievable, while guaranteeing as far as possible that the objectives of the programme are reached.

The Commission estimates the global needs for the whole duration of the Programme (1980-1984) to be 68,2 million EUA and 64 staff. 10 million EUA of the total 68,2 million EUA are already covered by the programme decision 1976-1980.

A compilation of some important achievements is given in Appendix I.

1. Introduction

On 15 March 1976 the Council adopted a research and training programme for the European Atomic Energy Community in the field of Biology-Health Protection (Radiation Protection Programme) for the 5-year period from 1.1.1976 to 31.12.1980. The budget allocation was 39 million EUA.
The present proposal for an extension of the Commission's Radiation Protection Programme is submitted pursuant to article 6 of the EAEC Treaty, taking into account recent progress of knowledge and the changing requirements for radiation protection in the Community which are factors leading to an evolution of the scientific content of the programme.

2. Role of the Radiation Protection Programme of the Commission

2.1. Objectives of research activities

The use of energy of nuclear origin, including the probable use of thermonuclear fusion in a more distant future, the handling of waste, effluent and fuels throughout their cycles and the various uses of ionizing radiation and radioisotopes, including medical diagnosis and therapy, are all factors calling for adequate prevention and control measures to ensure protection against ionizing radiations.

The role of this scientific research programme is to supply sufficient information to contribute to a framework for making informed decisions on issues on which public opinion has become very sensitive. Therefore, the Radiation Protection Programme of the Commission is designed to gain adequate understanding and control of radiation risks with two main objectives :

- improvement of scientific and technical knowledge with a view to updating basic standards for the health protection of the general public and workers against the hazards arising from ionizing radiation*.
- evaluation of the biological and ecological consequences of nuclear activities and of the use of nuclear energy and ionizing radiation, in order to ensure an adequate protection of man and of the environment whenever unacceptable harm could otherwise be caused to them.

---

* The preparation of basic safety standards for protection against ionizing radiation is one of the tasks incumbent on the Commission resulting from the Euratom Treaty.

It is evident that these objectives directly concern Community policies of undisputed importance : the social, the environment and the energy policies.

2.2. Coordination in radiation protection - a Community responsibility

Radiation hazards do not stop at national boundaries and the problems to which they give rise are basically similar in every Member State. Limited scientific manpower and financial resources contrast severely with the complexity and the extent of the problems to be solved. From the start of its activities in this area, the Commission accordingly made efforts to establish co-operation between the appropriate national institutes on work concerning the focal points of the programme. The success of these efforts is evidenced today by the fact that the majority of the national institutions and many of the university institutes active in this field are to be found among the participants in the Community programme. Unnecessary redundancy of work has been avoided and the best use of the available limited capacities is being achieved through dovetailing of the projects and joint planning arrangements.

This programme does not duplicate national efforts. It stimulates and complements them in topics of common interest. Joint planning and coordinated projects have appreciably improved the effectiveness of radiation protection research in the Member States.

3. Present situation in radiation protection research and its consequences

3.1. The Community's present research programme

The programme has yielded various types of results corresponding to important scientific progress. Statistically, during 1977, more than 600 scientific publications have resulted from this programme, and about 550 scientists belonging in almost all cases to national institutes, have joined in this work (corresponding to 300 scientists-years).From the published work a few examples of achievements are listed in Appendix I, although a complete evaluation of the present programme is premature since results are available only from the first two years of the 5-year period.

Besides the contribution from the present and earlier research programme to the worldwide compilation and evaluation of UNSCEAR and ICRP, the Commission's services have prepared monographs on special research subjects (e.g. treatment of acute radiation injury, risk evaluation of Ra^{-224}, collection of neutron dosimetry data, intercomparisons). Furthermore, the scientific data produced have been evaluated through the continuous activities of study groups in each of the programme sectors.

3.2. ICRP and UNSCEAR

Two important events characterize the present situation in radiation protection. On the one hand a very complete and updated compendium of scientific information on radiation effects, sources and risks, has been recently published by UNSCEAR*. This report evaluates, in view of risk estimates, research results on long-term somatic and genetic effects available up to 1977. Its influence on future radiation protection research will be considerable, especially as it sheds new light on many problems.

Moreover ICRP** has issued new recommendations. Following these, a revision of the basic radiation protection standards of Euratom is under way. Detailed guidance for their application has yet to be produced, especially as regards the introduction of new concepts such as detriment, collective dose equivalent, optimization and justification of irradiation.

Scientists who are actively involved in the Community's Radiation Protection Programme have participated in the preparation of both documents, and research results from this programme have contributed to the considerable increase of knowledge in radiation protection.

3.3. Consequences for the Community programme

3.3.1. Scientific reorientation

It is clear from the previous paragraphs that such changing concepts in radiation protection, should be reflected in any future programme. As a result changes in the scientific content proposed can be seen under point 4, where new subjects and priorities have been introduced.

---

* United Nations Scientific Committee on the Effects of Atomic Radiation.

** International Commission on Radiological Protection.

3.3.2. Organisational improvement : a rolling programme

Among consequences for the management of the programme, attention has to be drawn to the proposal of making a rolling programme, 1980 being an overlapping year. This is based on the following considerations :

- Modification and in some cases reorientation of research projects is a necessary consequences of the present situation. However such major reorientation could not be done easily during the last year of a programme. Considering the long duration of work needed in radiation protection research, it would seem better to allow a phased period to reorient for a new multiannual programme.

- The compulsory detailed evaluation of research projects, taking into account actual contracts and new proposals, would greatly benefit from an overlapping year, assuring thus evolution as well as continuity of the programme. Present contracts could come to their normal end or to be extended at the end of the overlapping year whilst new contracts could be started during its course.

- In the past the initial phase of contract negotiations was often very difficult for the contractors as well as for the Commission. For instance, due to the programme decision in March 1976, a first review of proposals by the ACPM could be done only in May 1976, and this then had to be followed by negotiations with contractors. Thus signing of contracts, which were to start on 1.1.1976, was delayed until the end of 1976.

- The number of excellent scientists working in radiation protection is very limited and it takes many years to build up good and serious research projects. Maintaining collaboration with excellent groups is a vital part of the programme. Thus it is regrettable that the Commission's services have to ask and try to convince contractors at the end of a five-year period to keep their research groups at work for about another year at their own financial risk until the signing of contracts legalizes the situation.

- Moreover if decisions on a possible continuation are not taken well in advance of the end of a contract, there is often moral pressure brought to bear on the services of the Commission and the ACPM to continue the contract. In fact, a late Council decision tends to limit unduly the possibilities of the ACPM to advise rejection or reorientation of proposed projects and of the contractors to dismantle research groups or to use them for other projects. Social problems for the research personnel engaged in contracts should be minimized.

All these factors point towards a decision for a rolling programme including 1980 as an overlapping year. The budget of the year 1980 will be completely covered within the upper limit of 39 million EUA of the period 1976-1980. Existing contracts will continue in 1980 until the date of termination which was originally foreseen in the contract or which would become necessary for other reasons. New contracts can be concluded in 1980 with a duration of up to 5 years to the end of 1984, following the lines of the new scientific programme.

4. The Radiation Protection Programme Proposal 1980-1984

4.1. Proposed research activities

The proposed Radiation Protection Programme of the Community endeavours, through a co-operative European effort, to increase knowledge in radiation protection while taking into account particular problems and skills available in Europe.

The programme will consist of six major activities or sectors which - arbitrarily but conveniently - serve to indicate its overall structure*:

- radiation dosimetry and its interpretation,
- behaviour and control of radionuclides in the environment,
- short-term somatic effects of ionizing radiation,
- late somatic effects of ionizing radiation,
- genetic effects of ionizing radiation,
- evaluation of radiation risks.

The information obtained from previous Commission research programmes and from research conducted elsewhere in the world in comparable fields has been examined, the present state of knowledge reviewed, especially as presented in the UNSCEAR report, future needs for practical protection measures and guidelines have been designed and the necessary research subjects identified.

The programme proposed by the Commission is based on foreseeable requirements of radiation protection in the Community and on the updating and adaptation of the activities already in progress, in the light of the expected development of nuclear facilities and other sources of ionizing radiation and of their possible effects on man and the environment. It is necessary to stimulate research on various subjects which are of crucial importance for the future and proposals to this effect are outlined in the following pages.

---

* No such subdivision can adequately define the complex scientific content of a balanced radiation protection programme. There is an apparent overlapping between sectors and there are subjects related to all or several of the sectors. Dosimetry, for example, is a basic requirement for all sectors, synergistic effects are observed under many different conditions and the problems of low doses or low dose rates, as well as of the fundamental mechanisms of the observed effects or the need for epidemiological studies manifest themselves in several sectors.

4.1.1. Radiation dosimetry and its interpretation

Application of regulations for radiation protection and research on effects of ionizing radiation can only be carried out properly if it is possible to determine absorbed dose and/or other exposure parameters and interpret them in terms of biological effects and the risks to which they give rise. Furthermore the directives of Euratom on Basic Standards require the measurement and recording of certain exposure data which should be carried out in a comparable manner within the Community. Thus the following subjects require further investigation in support of the Radiation Protection Programme as a whole.

- Physical aspects of radiation effectiveness (Microdosimetry)

  Biological effects of ionizing radiation are dependent on different irradiation parameters, especially on the radiation quality, interpreted as the spatial and temporal distributions of radiation energy absorption and transfer to biological tissues, the distribution of energy deposition within sensitive sites, as well as the immediate biochemical effects. Despite the considerable progress made in the acquisition of the necessary physical data, more detailed investigations are required to establish convincing relationships between the form of radiation interaction and the dose-effect curves for external radiation and incorporated radio-nuclei. Microdosimetric research on tumour induction and defects of organ function should be able to contribute to the solution of such urgent problems in radiation protection as whether the relative risks from low doses and dose rates of both low and high-LET-radiations have been over or under-estimated,and any changes needed in Quality Factors, with all the impact that such changes might have on shielding design and personal dosimetry.

- Internal dosimetry

  Research is needed to develop further quantitative methods to assess the effective radiation dose in the case of incorporation of radioactive isotopes such as tritium and the transuranic elements and the inhalation of radioactive aerosols. The

improvement of dosimetric models used by ICRP for the lung, the gut and the bone, estimation of lung and body content of alpha-emitting radionuclides by whole body counter and excretion measurements respectively, and effects of labelled DNA precursors in the cell nucleus are of particular relevance for radiological protection.

- Dosimetry in case of external irradiation

External irradiation usually gives rise to quite inhomogeneous dose distributions or to partial body irradiation making it sometimes difficult to establish the dose in irradiated organs or tissues under risk. Therefore physical methods have to be improved in order to relate field characteristics of external radiation, such as exposure and quality and differences in tissue densities, more accurately to the organ dose.

- Personal dosimetry and area monitoring

Following the recommendations in recent ICRP publications the revision of radiation protection standards needs to be backed up by research into methods aimed at applying and evaluating these recommendations. The introduction of the effective dose equivalent and the dose equivalent index means that existing measuring methods have to be adapted and conversion factors and functions have to be theoretically and experimentally established for the different quantities, especially as regards instrument calibration.

There are various ways of carrying out personal dosimetry in the individual countries. An analysis will be made of parameters such as internal and external irradiation, contamination, incorporation and excretion which must be determined, in order to make decisions on risk estimates both for acute and chronic exposures and therapeutic measures. Measuring methods will be developed and coordinated. Research is required on protection standards for beta-particles and on the information needed for this purpose. Information from intercomparison programmes and field studies will complement the research results.

- Dosimetry of high-LET-radiation and neutrons

  Concerted support is presently necessary to achieve data on high-LET-radiations including neutrons of selected energies of practical importance. Although many physical data and measuring methods for neutrons have been published or elaborated in recent years, completely satisfactory methods in personal neutron dosimetry as well as for neutron and high-LET-dosimetry for radiobiological experiments have yet to be devised. One problem will certainly be to collect and evaluate data that will enable a general consensus to be reached on neutron dosimetry itself. In this area also intercomparisons require a continuing effort, since those which have been carried out have revealed unexpected discrepancies in dosimetry procedures and accuracy.

A programme of continuing development and adaptation for all dosimetric methods - as has taken place in the past - is required to deal with changing needs of radiation protection. For this, some flexibility of approach is needed to tackle mission oriented problems or to carry out exploratory studies of actual needs, or to develop new instruments, thus guaranteeing flexibility and capability for innovation in the future.

- One such problem will be environmental dosimetry. A more realistic estimate should be made of the dose to the public resulting from natural radioactivity and enhanced natural exposure. This forms part of the proper assessment of the risk from man-made radiation sources.

- Another problem of increasing concern is exposure in medical diagnosis. This makes the greatest contribution of any man-made radiation source to the general population. Dosimetric research will aim at reducing the non-essential dose from this exposure while maintaining the quality of the diagnostic information. It will also examine the usefulness of such data for epidemiological studies of radiation effects.

- Still another problem is the possibility of using biological dosimetry for accidents to provide important additional information on the effective dose received. Unfortunately these methods have not proved entirely sufficient in certain accidental situations. Research is needed on the improvement of reliable biological dosimetric methods and on the influence of a wide range of dose rates and non-uniform spatial dose distributions on the biological indicators.

4.1.2. Behaviour and control of radionuclides in the environment

The programme of this sector is directed to the acquisition and improvement of data on the behaviour of particular radionuclides in various parts of the environment. Such data are an essential input to assessments of the radiation detriment, in terms of potential harm to health, of routine activities and events (such as accidents) which result in the release of radioactive materials to the environment (see section 4.1.6.). Important subjects, unconnected with nuclear power, which will be included in the programme are those human activities which cause man to be exposed to natural background radiation to an enhanced degree.

The assessment of the detriment requires the estimation of individual and collective doses in the exposed population, usually by means of models which represent the way in which radionuclides are tranferred along various and often complex environmental pathways.

In addition, the acquisition of these data will assist those who are responsible for authorizing the discharge of radioactive materials and setting suitable limits for such discharges to the environment and it will also improve the scientific basis of environmental monitoring programmes.

Many data have already been accumulated on the behaviour of several radionuclides in particular sectors of the environment, for example, from studies of fallout from the atmospheric testing of nuclear weapons and from laboratory experiments. However, many gaps remain and many of the data which are available need to be improved in quality.

In the conduct of this programme a reasonable balance between laboratory and field experiments will be necessary ; although there is an increasing need for field work to confirm the validity of transfer coefficients derived from laboratory experiments.

Useful information on the reliability of transfer coefficients and on any unexpected sources of contamination might also be derived from data recently collected in several monitoring programmes.

Priority will be given to those radionuclides and environmental pathways which are likely to be important in nuclear power programmes in the coming decades or as a result of radioactive materials that may be introduced into the environment from other sources. In compiling the detailed programme, account will be taken of other Community programmes (see footnote) relevant to nuclear safety and environmental protection thus ensuring that appropriate liaison will be established.

Reviews of existing data and anticipated practices at various stages of the nuclear fuel cycle indicate that the following are <u>important activities in the context of the programme</u> :

- Uranium mining and milling
- uranium enrichment plants
- reprocessing of irradiated fuels
- recycling of uranium and plutonium and the fabrication of mixed-oxide fuels
- the introduction of advanced reactor systems
- the possible introduction of alternative fuel cycles
- decommissioning of nuclear reactors
- the management, including disposal, of the liquid, gaseous and solid wastes that may be generated by all the above activities.

Particular attention will be paid to methods of estimating contamination levels, demarcating contaminated areas and reducing or eliminating radionuclides transfers in accident situations.

Radionuclides which presently appear the most important are the transuranic elements and also H-3, C-14, S-35, Kr-85, Tc-99, Ru-106, I-129, I-131 as well as some activation products (Mn-54, CO-60) and natural radioisotopes (radium, thorium and daughter products). The chemical toxicity of some of these nuclides (Tc-99, I-129) must also be considered.

- Programme on management and storage of radioactive waste
- Programme on plutonium utilization
- Programme on uranium exploration and extraction
- Programme on decommissioning of nuclear power plants
- Programme on safety of light water reactors.

The main environmental transfer processes requiring further investigation are summarised below :

- resuspension of radionuclides from the sea surface, silts and typical European land surfaces (particularly for Np, Pu, Am and Cm and long lived fission products) ;
- the transfer of radionuclides deposited on the surface of agricultural land to soil, water, plants and animals (particularly for the transuranium nuclides, members of the thorium and radium decay chains and other radionuclides including S-35, Tc-99, Ru-106, I-129). The way in which the systemic contamination of animals might be influenced by the incorporation of radionuclides in biological materials and by chronic exposure conditions needs special attention ;
- the migration and retention of radionuclides in a range of rocks and soil types typical of Community countries (particularly for the transuranium nuclides and long-lived fission products) ;
- the transfer to sediments of radionuclides released to the aquatic environment, and their possible remobilisation (particularly the transuranium nuclides and long-lived fission products) ;
- the regional distribution and behaviour of long lived radionuclides (e.g. C-14, Tc-99, I-129) with particular reference to their exchange between different sections of the environment (e.g. exchange between the aquatic and terrestrial environments);
- the uptake by aquatic species of particular radionuclides (e.g. Tc-99) where more information is needed ;
- the investigation of possible synergistic effects of radionuclides and conventional pollutants released to the environment, with particular reference to uptake of radionuclides into food chains ;
- the exchange of C-14 and HTO between the atmosphere and terrestrial environment ;
- the atmospheric dispersion and deposition processes in urban areas.

4.1.3. Short-term somatic effects of ionizing radiation

Radiation injury occurs at the time of exposure. All subsequent biological effects depend essentially on the rapid changes occurring during an extremely short period of time following the energy absorption. A detailed knowledge of these events would allow to understand the mechanism of the radiation effects.
For many years it has been known that free radicals and their reaction products play an essential role during the early phase of the radiological damage but only recent technological advances made it possible to measure and to identify them in biological material. In relatively few years great progress was made and nowadays, the reaction of radio-induced free radicals with nucleic acids which are the main biological target of radiation are fairly well known. Further studies in this field, if well coordinated, should give us a clear understanding of the primary mechanism of the radiation damage which would be invaluable for the comprehension and possible control of the consequences of irradiation on living matter.

The study of the early cellular and tissue effects of radiation injury from internal or external origin will be intensified in view of their increasing importance in industry, research and clinical medicine. Lesions which are amenable to treatment include mainly localized radiolesions and damage to the lympho-hemopoietic system. These pathogenic studies will be of basic importance for the development of therapeutic strategies.

Because of the high incidence of acute, subacute or chronic local radiation injuries, the study of their mechanism, prognosis, complications and treatment will be given special attention. Depending on the great variety in the modalities of irradiation, including external as well as internal irradiation (absorption of radioactive material by ingestion, inhalation or wound), they may involve not only the skin but also internal surfaces like those of gastro-intestinal tract, the respiratory tract and many other organs. The connective and vascular tissue which is present almost everywhere in the body deserves particular studies with regard to possible late effects. The high incidence of cancerous transformation following the healing process is

also typical for radiation burns. Therefore, the pathogenesis of these lesions, of the complicating factors and of the mechanism and the kinetics of cellular repopulation will be thoroughly investigated. Also the study will consider the characteristics of antigenic changes and possible neoplastic alterations of the damaged tissue, the role of damage to the immune system and the specific problems encountered when skin-graft therapy is applied.

Early effects of radiation injury to the hemopoietic system by total or subtotal body irradiation and the therapy of those injuries have been studied in previous programmes and considerable progress has been made in understanding and treating the "bone marrow syndrome". However, assessment of the impairment and regeneration potential of the hemopoietic function by existing methods of diagnosis is not yet optimal particularly with regard to the diagnosis of damage to stem cells and to certain populations of lymphocytes. Therefore, the use of chromosomal preparations and other monitors of radiation damage will be studied. As far as therapy is concerned several problems continue to require attention. New radioprotectors have recently been discovered which, if further investigated, could be valuable for human application. Problems of an immunological nature remain a major difficulty, although advances in immunology have greatly improved the feasibility of marrow transplantation in man. These advances include : the removal of immunologically reactive lymphocytes from the marrow suspension (stem cell separation); vastly improved tissue typing and cryopreservation of stem cells (marrow banks) and the feasibility of "manipulating" the immune reactivity which plays a central role in the fate of patients who are treated with a marrow graft (immune-deficiency is the most serious late complication). This part of the research programme will therefore emphasize immunological problems such as :

a. further improvement of matching for newly discovered tissue antigens;
b. separation and cryopreservation of stem cells, including a standardized method of assessing their viability;
c. monitoring and enhancing the immune reactivity of the marrow treated recipient to prevent late complications (infections and possible radiation-induced neoplasia).

4.1.4. Late somatic effects of ionizing radiation

Two types of harmful effects may be induced by radiation and some of these may only become manifest long after initial exposure. In one type, involving the so-called "stochastic effects", the frequency with which the effect occurs depends typically upon the size of radiation dose, but the severity of the effects does not in general depend upon the dose. The induction of malignant disease constitutes the most important example of such effects.

In the other type, involving "non-sotchastic effects", no significant harm is ordinarily detectable below a certain dose but the severity of the effect which is then produced may vary with the size of the dose. The induction of cataract or of reduced fertility, and the impairment of organ function or blood supply represent changes of this type.

- Induction of stochastic effects

a. Human observations : Malignant changes induced by radiation are of particular importance in regard to radiation protection. The Commission therefore emphasizes the continuing need for assessing the frequency with which different types of malignancy occur in excess of normal expectation in groups of people who have been irradiated (for medical or other reasons) at known dose levels, and have been or can be followed up comprehensively for long periods of time, ideally for several decades, during which further radiation induced tumours may become detectable.

Special attention should be given to dosimetry, length and efficiency of follow up, comparability of the control series, influence of sex, of age at the time of exposure, mortality resulting from radiation-induced tumours, the way in which the latent interval between irradiation and detection of tumours varies with dose or with other factors, the influence of the quality of the radiation (LET), variation of this influence (RBE) with dose, and the form of dose-effect relationship.

Groups of patients who have received repeated or extensive diagnostic radiological investigations will be studied whenever full records such as the frequency of death from malignant disease are obtainable.

Statistical studies of patients who had received internal or external radiotherapy at moderate dosage, particularly in the treatment of non malignant disease should yield additional risk estimates for cancer induction in relevant organs. These results will only be meaningful if control values can be established for the incidence of cancer in patients with the same diseases but who had not been treated by radiation. Such studies should also give some guidance on the safety requirements for these forms of therapy. Similar studies on the effects of radiotherapy for malignant disease, whether given alone or in combination with chemotherapy, could also assist in defining the possible after-effects and the appropriate forms of treatments to minimize the frequency of such hazards. In addition, these studies may throw light on possible synergism between radiation and chemical agents, or a greater sensitivity to radiation carcinogenesis of particular tissues in certain diseases.

b. Animal studies : in order to elucidate the mechanism of cancer induction, there is an evident need for fundamental experimental studies of the nature of this phenomenon, and of the frequency with which malignant changes are likely to be induced especially by low doses and low dose rates. Such information can form a basis on which valid inferences can be made on the frequency of malignant change to be expected following the even lower doses involved in occupational or other exposure to radiation.
Dose effect relationships at low doses, microdosimetric studies, comparison of high and low LET radiation and of dose protraction will be carried out.
Studies concerned with events after incorporation of radionuclides will take into account the following parameters : uptake (by ingestion, or inhalation), radiation quality, biological half life, organ distribution, affinity to particular tissues, inhomogeneity of deposition, metabolism and excretion and studies on the benefit or possible harm of chelating agents.
Special emphasis will also be placed on the variation of factors which are likely to influence the carcinogenic process. These factors include age, sex, hormones, viruses, the immune system and local tissue reactions as endogenous, and some aspects of cocarcinogenesis and synergistic effects as exogenous factors.

The exact identification of the cells at risk and of the early and intermediate sequence of events during carcinogenesis will necessitate the development of new methods (including biochemical and immunological markers). Furthermore, the link between mutagenic and carcinogenic effects should be elucidated.
Standardization of animal experiments, of tumor nomenclature and quantification of morphological endpoints will be continued.

- Induction of non-stochastic effects

In determining the procedures and the dose limits appropriate in radiation protection it is important to know the types of non-stochastic effects which may be induced by radiation in man, the severity of these various effects, and the dose level at which they are liable to be induced. It is particularly important to have information on those effects which might be induced by doses amounting to a few tenths of a sievert each year continued over many years or decades.

This practical requirement applies especially for those tissues or organs in which the rate of fatal cancer induction per unit absorbed dose is likely to be low since for tissues like bone, skin and thyroid the annual dose limit is less likely to be determined by the possible induction of malignancies than by that of harmful non-stochastic changes.

Information will be sought in man and in animals on the total accumulated dose delivered over a substantial proportion of a human or an animal's lifetime which would cause the same effects as are produced by a single dose.

Guidance on these questions needs therefore to be obtained from a review both of effects caused in man and those induced in animals experimentally. In man it is important to survey the dose above which various non-stochastic effects are observed, particularly in the course of radiotherapy at which the appropriate dose levels are reached, but including where possible, the effects of radiation at high LET and those of treatment with radionuclides where relevant. Study of the pathogenesis of these effects is likely to throw light

on the importance of mechanisms of repair.

In this connection it is also necessary to assess the nature of any differences between the reactions of normal and diseased tissues to radiation. In many cases it is to be expected that the accumulated doses which give rise to malignant changes in a tissue will also have caused or initiated non-malignant changes. Any interactions between the development of these two types of effects or the influence of non-malignant changes on the frequency of cancers are important. The examination of the early phase in development of late non-stochastic effects could also prove important for assessing the probability of such late effects.

In relation to the hazard involved in any radiation exposure during pregnancy, teratogenic effects will be studied, particularly with regard to the following : possible existence of a threshold, influence of LET, possible inactivation, recovery or repair of embryonic cells, relationship between damage to single cells of the embryo, major failures in development of the foetus, dose/effects relationship at various stages of embryological development.

The frequencies with which different types of developmental defect (most commonly of the nervous system) are induced by radiation in man and in any experimental model should be as close as possible.

A non-specific shortening of the life span by ionizing radiation still remains uncertain , but its mechanism would call for study if its existence were experimentally proven.

4.1.5. Genetic effects of ionizing radiation

The study of radiation effects on genetic material is important because radiations may increase the incidence of chromosomal syndromes and of hereditary diseases and because detailed analyses are required of the complex pathways through which the irradiated cell deals with pre-mutagenic and pre-carcinogenic lesions. Thus, the general objectives in this sector are to provide the information needed for :

- assessing, through the use of the methods currently available (direct estimation method and doubling dose method), the genetic damage induced by radiation in man. The knowledge required for this purpose includes estimates on the birth frequencies of genetic diseases, determination of the values of doubling doses and an evaluation of yields of genetic defects per rad.

- understanding the factors which govern, modify or prevent the establishment of damage. The research carried out in the past now renders possible the genetical and biochemical characterization of some of the processes of DNA repair in human cells. A stimulation of the research on the elucidation of mechanisms may not only allow a continuation of this work but, ultimately, it could provide new means for predicting interactions and effects, for establishing relationships between mutagenesis and carcinogenesis and for preventing or protecting against radiation damages. It should also accelerate the development of methods for the detection of sensitive individuals and, among these, of individuals who are heterozygous for genetic diseases involving a repair deficiency and have an increased sensitivity to mutagens and carcinogens.

For reaching these objectives, in the programme proposed below, emphasis is placed, whenever possible, on the direct analysis of human systems. However, the use of experimental species is maintained in all instances where there is no reliable alternative.

- Assessment and analysis of genetic damages in eukaryotes

The gene mutations and chromosome aberrations which occur spontaneously in man are a source of considerable hardship, being responsible for a substantial fraction of all spontaneous miscarriages and, in full-term survivors, congenital malformations, mental and physical disorders. The incidence of naturally occurring hereditary defects and diseases in human populations has been calculated by UNSCEAR to be approximately 1.0 per cent for dominant and X-linked diseases, 0.1 per cent for recessive diseases, 0.4 per cent for chromosomal diseases and 9.0 per cent for congenital malformations, multifactorial and irregularly inherited conditions. It is thus particularly important, in view of the fact that irradiation is known to induce mutations and chromosomal anomalies, to improve as much as possible the present methods of detection of genetic radiation effects and to establish, through an analysis of the mechanisms of induction, the list of various factors and circumstances which may contribute to an enhancement of incidence rates.

Since human systems are usually not amenable to detailed genetic analyses, a substantial portion of the research effort will be carried out through the use of other eukaryotic material where the similarity of chromosomal organisation (DNA, histones ...) and of cellular organelles implies that many of the induction mechanisms for damage in the nucleus and in the cytoplasm are identical to those of man. The programme involves :

a) the improvement and development of assay systems and experimental methods with increased resolving power for the detection of induced alterations in both somatic and germ cells of man,

b) elucidation of the mechanism leading to chromosomal non-disjunction and other aberrations including studies of the relationship between chromosome structure and behaviour (heterochromatin, synaptinemal complex and satellite association).

c) study of possible associations between radiosensitivity, repair and segregational anomalies,

d) specific studies on the interactions and relationships between the biological effects of radiation and other environmental agents,

e) elucidation through a few selected studies, of the effects of irradiation on the mitochondrial genome and its implication for cellular survival.

- Dose-effect relationship

It is particularly difficult to establish the relationship between dose and effect in man because insufficient human data are available and because the quantitative extrapolation of experimental results to man poses serious problems. In view of the importance of dose-effect relationships for the assessment of radiation risk, the programme includes :

a) epidemiological surveys which focus attention on the relationship between the dose received, the frequencies of aberrations in lymphocytes and the long term biological consequences of the exposure (aplasia in germinal cells and induced effects in live-born and still-born children),

b) determination of the in vivo kinetics of lymphocytes with the view of facilitating the interpretation of doses from non uniform exposures,

c) investigations with mammalian experimental species (including primates when possible) designed to collect more data (genetic as well as cytogenetic) which will be useful for quantitative extrapolation of radiation genetic hazards to man,

d) studies aimed at the appraisal of the methods and assumptions involved in risk assessment in extrapolating from somatic to germ cells and from experimental species to man,

e) studies on the induction of mutations in germ cells and somatic cells at very low doses and dose-rates and the development of techniques to facilitate such studies.

- Biochemistry and genetics of radiosensitivity and repair

As a consequence to the elucidation, now well in progress, of DNA repair pathways in microorganisms, research involving the use of human cells having mutations leading to repair deficiencies has shown that the mechanisms for repairing DNA damage are of great relevance to human health. Several specific factors affect repair capacities and a number of hereditary diseases that are accompanied by an increased sensitivity to radiation and incidence of cancer are associated with defects in DNA repair.

A large part of the envisaged research is to be executed on mammalian, and particularly human, systems but the use of non-mammalian material will be necessary for the analysis in depth and the modelling of complex biochemical and genetical mechanisms.

The programme will include :

a) surveying the radiosensitivity of a variety of human cells (fibroblasts, lymphocytes, etc ...) taken from normal "control" group as well as from representatives of those human diseases showing enhanced sensitivity to environmental mutagens. Whenever possible, a detailed analysis of variations in radiosensitivity between individuals will be undertaken,

b) identification, and genetical and biochemical characterization of variant mammalian cell strains of differing sensitivity and deficient in repair of DNA damage,

c) investigation of the detailed enzymology of DNA repair pathways (this is best studied at present in microorganisms where formal biochemistry and genetics are well established) and studies of the biochemical specificity and biological significance of DNA lesions in mammalian systems. This will include the use of proteins that recognize specific lesions as analytical probes for monitoring enzymatic repair and the relationship of lesions to mutation, recombination and chromosome aberrations,

d) studies of mutagenesis and the role of constitutive and inducible repair pathways in mammalian cells. Use will also be made, in this part of the programme, of the several DNA repair deficient mutants recently isolated in Drosophila which provide an opportunity for studying the role of DNA repair pathways in the realization of radiation induced genetic damage in an eukaryotic model system,

e) analysis of the relationships of DNA repair and related mechanisms to carcinogenesis.

4.1.6. Evaluation of radiation risks

Concepts used in radiation protection are liable to be applied in different ways in the Member States. For this reason, it is necessary to attempt to establish common methods for assessing as accurately and objectively as possible the consequences of irradiation for man and his environment. The results of such exercise are also needed for decision making on siting and on choices for energy supply.
The new principles of optimization and limitation in radiation protection, which have been recommended in 1977 by ICRP, are based on a risk and detriment concept and require the assessment of realistic relationships between dosimetric quantities and genetic and carcinogenic risks. New dosimetric quantities and concepts have been developed; among them are the effective dose equivalent and the dose equivalent index for the description of individual exposure, and the collective dose and the collective dose commitment for the assessment of the collective health detriment. The practical application of these new terms has to be tested and their relationship to measurable quantities has to be determined.

Three groups of problems must be considered.

The first is the assessment of the individual and collective doses resulting from normal discharge and accidental releases of radioactive substances. This assessment of doses must rely on data obtained by studying the movements of radionuclides in the environment as described under 4.1.2., and should lead to a better determination of the dose distribution among the population and the magnitude of the collective dose taking account with the natural background. Models are required also for any likely pathways of access to man and his environment, and involving the entire nuclear fuel cycle.

As regards optimization in radiation protection which is currently advocated, account must be taken also of all the risks arising from human activities which make use of ionizing radiations or influence irradiation, such as those involving medical applications and technologically enhanced radioactivity. The programme will comprise successive phases of identifying the points to be studied, of assessing the doses received by workers and by the public, and of research

into possible protection measures and their cost.

The second problem is methodological research on the assessment of the detriment. It must make use of data obtained through experimental and epidemiological research described in the relevant sectors of the programme. Two groups of problems should be considered. Firstly, those of the assessment of the detriment in the case of medium and high level irradiation, applicable in the event of an accident. Secondly, those related to low doses, which are particularly relevant for all occupationaly exposed persons.

The third problem is the assessment of the economic and social consequences of irradiation. This is a new subject which should be developed in order to establish guidelines for "optimization" of radiation protection activities based on the attainment of "as low as reasonably achievable (ALARA)" levels under conditions which apply in Europe.

4.2. Implementation

The implementation of past programmes has shown that an "indirect action" combined with an efficient management with the help of the ACPM and based on careful evaluation are the appropriate means for carrying out this Community research programme. Some aspects of this system can be improved, but in any case it always has to keep the administrative charge for contractors and scientists as low as reasonably achievable.

4.2.1. Participating laboratories

Continuing the policy which has operated from the very beginning of the programme, the Commission will endeavour to organize co-operation through cost-shared contracts with the appropriate national and university institutes working on the various focal points of the programme. Co-operative action and an organized distribution of tasks are necessary in view of the limited resources, the great number of different scientific aspects of radiation protection research, and the geographical scattering of those research groups which have the necessary specific competences. In addition, the work of the Commission's Biology Group at Ispra will continue to be an integral, but small part of the programme, supplementing and supporting certain research carried out in the contract programmes.

4.2.2. Management

The Commission with the advice of the ACPM will be responsible for the management of the programme and its contracts and will ensure a close liaison with the corresponding research and development carried out in the Member States. Obviously the ACPM has a direct influence on the management of the Community's Radiation Protection Programme and, owing to the national status of its members, indirectly on that of the Member States.

4.2.3. Coordination

The best possible implementation and coordination is a main concern of the ACPM when it evaluates research proposals and contracts and advises on their relevance and integration into the programme and the selection of laboratories to which the work is to be entrusted.

Particular attention will be given to coordination throughout the programme. Study group meetings, symposia and conferences have proved to be a most effective means of coordination because they are naturally adapted to scientific work and easily accepted by the scientist. These meetings, focussing on the evaluation of particular subject areas of the programme, will be attended by research workers involved in the contract programme, as well as scientists from non-participating laboratories or organizations and scientific staff members of the Commission.

Existing facilities for exchange of information and experience between the contractual partners should be supplemented by arrangements for working visits of limited duration by research workers engaged on the contract programme. Past experience has shown the benefit to the Commission's partners of improving the mobility of research workers by enabling them to work for periods ranging from a few months to two years in laboratories taking part in the programme.

Working relations with the main international organizations active in the field of radiation protection will be maintained.

4.2.4. Evaluation

Since the creation of the ACPM in 1968, mechanisms for evaluating programmes have been developed but a higher degree

of flexibility was necessary to apply them to radiation protection research. Universities and national institutions are collaborating in the programme, in disciplines as different as immunology and statistics. Evaluation will be undertaken by the ACPM and the Commission's services on three levels:

The evaluation of research proposals before the beginning of a project: Accepting or rejecting them, changing and adapting the proposed projects in accordance with the agreed programme guidelines.

Annual evaluation in the course of a project, for approval, modification, reorientation or possible new suggestions for contractors:

- Results achieved are examined and evaluated annually when the Commission presents the Progress Report on "Radiation Protection" detailing the results of the previous year of all projects. In this respect the scientific publications, drawing attention to the results in the Community programme, of which reference is made in the Progress Reports, constitute a major element for evaluation.
- Likewise annually the planned activities for the coming year are evaluated when discussing the "Work Programme of the Next Year".
- Finally, special subject areas are evaluated in study group meetings and direct individual contacts.

The evaluation of results at the end of projects: Final reports and synthesis reports such as monographs are used to this end.

4.2.5. Dissemination of results

The scientific research results of the programme are presented in articles published in scientific journals, in Euratom reports, in monographs issued by the Commission, and in the proceedings of symposia and seminars.

4.3. Funds

The Commission will aim for maximum efficiency in the use of the funds entrusted for the execution of this programme. As it is essentially an indirect action programme, the contracts must be allocated the major share of the funds.

4.3.1. Staffing

The Commission proposes a staffing of 64 officials for the period 1980-1984. In this respect it has to be recalled that in 1973 97 staff were authorized and in 1976 68 staff in addition to which 10 local agents for the Biology Group at Ispra were foreseen in the budget.

4.3.2. Financial allocation

The Commission has evaluated the global needs for the programme at 58,2 million EUA for the period 1981-1984 to which will be added about 10 million EUA for the year 1980, which are already covered by the budget allocation of 39 million EUA for the period 1976-1980.

This is certainly a substantial increase in absolute figures as compared with the actual programme. However, in view of the generally accepted great social relevance of radiation protection, its importance for energy production, and the resulting high requirements in radiobiological research, this amount is estimated necessary to establish a well balanced programme covering all priority aspects. Its content is based on a reorientation and evolution of the present programme, an evolution which accentuates new aspects as the evaluation of radiation risks and the treatment of acute irradiation, particularly when local.

Expansion will be limited and will affect only the contractual activities, which will be allocated more than 81 % of the total funds (less than 7 % for management and administration of the programme).

The following particular elements have been used as a base for the budget estimate of 58,2 million EUA:

- the expenditure of the year 1980, originally planned as the last year of the current programme (1976-1980) (10 million EUA);
- the need to take account, in some measure, of the increase of costs (+ 6% per year);
- the restoration of the Commission's participation in contract expenditure from an actual mean of 33% to its previous level of 40%. This guarantees a significant Commission presence in the combined effort being made in Europe in radiation protection research and in particular allows the mobility of research workers in European laboratories;
- a limited expansion (+ 15% of the contractual activities).

The amount of 10 million EUA for the year 1980 is completely covered by the budget allocation of 39 million EUA for the period 1976-1980. It corresponds to

- staff expenditure, recurring administrative expenditure and expenditure relating to the use by the Biology Group of the scientific and technical services of the Ispra Joint Research Establishment, as requested for the 1980 budget,
- the Community's financial contribution to contracts relating to the year 1980 or as appropriations outstanding from earlier years authorized within the ceiling of 39 million EUA of the 1976-1980 programme;

The amount of 10 million EUA for the year 1980 is the result, not of any real expansion, but of the following factors:

- inflation rated during the period 1976-1980
- the influence of "gross salaries" as opposed to "net salaries" which were previously taken into account.

The summarized calculation is as follows:

Budget 1980	10,0 million EUA
Budget 1981-84 based on budget 1980 + 6 % increase per year	46,4 million EUA
Restoration of 40 % mean participation in contracts	+ 6,9 million EUA
Expansion of certain activities based on an increase of 15 % of the contracts	+ 4,9 million EUA
TOTAL 1981-1984	58,2 million EUA
TOTAL 1980-1984	68,2 million EUA

4.3.3. Financial breakdown

As a guideline, expenditure by categories is broken down in the following manner:

million EUA

	1980	1981-84	Total	%
Contractual activities:	7,770	47,800	55,570	81
expenditure for contracts, cash	(5,850)	(38,9)		
expenditure for Commission personnel working under the contracts	(1,920)	(8,9)		
Biology Group at Ispra:	1,410	6,500	7,910	12
expenditure for research	(0,110)	(0,5)		
infrastructure and technical support	(0,330)	(1,5)		
personnel	(0,970)	(4,5)		
Management and administration:	0,830	3,900	4,730	7
expenditure for experts' fees, meetings, etc.	(0,140)	(0,7)		
headquarters personnel	(0,690)	(3,2)		
TOTAL	10,010	58,200	68,210	100

RESEARCH WORK 1976-1978

- A survey of some scientific achievements -

The research results obtained from the European Communities' Radiation Protection Programme help to extend the scientific basis on which a reliable evaluation of the biological and ecological consequences of using ionizing radiation and of activities in the field of nuclear technology can be made and the best possible protection can be provided for man and his environment. These research projects contribute to obtaining a more accurate assessment of the radiation risk and to reduction of uncertainties and contradictions.

The programme currently comprises 130 contracts with about 240 research projects; more than 500 research workers are participating on either a full-time or a part-time basis.

In the first three years of the current programme, about 1.800 individual articles have been published; numerous monographs, proceedings and technical reports on radiation protection subjects provide evidence of intense scientific activity.

Every year, about 40 symposia, seminars and meetings of study groups, experts and committees with about 1000 participants ensure coordination and stimulation and have a catalytic effect on national, bilateral and multilateral programmes.

In executing the programme, the Commission bore in mind the facts that:

- sociopolitical objectives are increasingly becoming criteria for radiation protection research policy;
- the individual research activities should be more closely harmonized in a broader context.

With the means at its disposal, therefore, the Commission has:

- developed long-term research programmes;
- intensified research in areas of great significance to the public (e.g. evaluation of the radiation risk);
- promoted the practical application of scientific results (e.g. development of personal dosimeters, diagnosis and treatment of acute radiation injury, execution of inter-comparison programmes);

- prepared longer-term forecasts (e.g. tritium study);
- given its backing to the rapid translation of scientific knowledge into decision-making processes (e.g. establishment of basic safety standards, formulation of criteria for siting-decisions).

In approach to its work, the Commission employed the following criteria which have had a beneficial influence on research in the Community:

- intensification of interdisciplinary fields of research and co-operation in the projects being promoted (e.g. group contracts, EULEP, CENDOS, Primary effects group);
- improvement of information exchange and co-operation between scientists engaged in similar fields of work (e.g. study groups, conferences, exchanges of scientists);
- adaptation of research projects to scientific progress (a permanent task in co-operation with the ACPM).

Only a few individual projects of the wide range of scientific results obtained over the last years can be briefly described for the sake of example. For this reason, a number of details from the areas of dosimetry, environmental contamination, somatic and genetic radiation effects and risk analysis have been selected and presented.

Radiation dosimetry and its interpretation

The main objective of dosimetry is to obtain reliable measurements and calculations of absorbed dose and dose distributions. They are necessary to improve understanding of the biological effects in order to make a proper assessment of the radiation hazard and they are essential to assure protection of exposed workers.

- Co-operative research in radiation protection depends largely on the degree of standardization of experimental methods and materials. A number of dosimetric intercomparisons have therefore been carried out, for instance on personal dosimeters, on X-ray dosimeters and with neutrons. All these intercomparisons revealed quite a number of imperfections in experimental arrangements, differences in the basic values used to determine the absorbed dose, and discrepancies in dosimetry procedures. The intercomparisons induced a considerable improvement in research procedures, and increased the accuracy and reproducibility of the measurements. For example, in the last X-ray intercomparison series it was found that previously-observed large standard deviations of results from several laboratories could be eliminated, especially after visits had been made to the laboratories.

- The measurement and calculation of underlying parameters in dosimetry have made important progress. A low-energy electron transport simulation (10 eV - 30 KeV) in water was satisfactorily terminated; cross-sections, stopping powers and W-values for different materials and different particles were measured and the cross-section library in transport codes improved. Some problems of measurement of the components of a mixed neutron and gamma radiation field were solved; the track structure of electrons and charged particles and the production of secondaries and their radial distribution were investigated. Microdosimetric quantities were established and extended to tissue regions of 10 to 100 nm diameter; they have been used in defining a measure of radiation quality and in microdosimetric models developed for the interpretation of mutation and survival data from mammalian cells.

- The investigation of fundamental mechanisms in radiation physics has indicated interesting possibilities in the use of lyoluminescence in radiation accident dosimetry, since some human tissues have lyoluminescent properties.

- Fundamental aspects of the mathematical analysis of tumour induction by ionizing radiations have been investigated. Statistical methods for the assessment of tumour rates and of tumour prevalences as a function of time after irradiation were tested. It was possible to prove a statistically significant increase in the development of mammary tumours in Sprague-Dawley rats at fast neutron doses as low as 0,1 rad. The relative biological effectiveness (RBE) of these neutrons seems to reach values of 100 or more at low doses. At higher doses the RBE decreases to values already known from other experiments.

- Radionuclides with low energy beta-particle or Auger electron emission incorporated in various organs, cells or subcellular structure were shown to cause biological effects which largely depend on the spatial overlapping of the site of decay and of the radiosensitive structure. The critical microvolume for late effects appeared to be the nucleus of stem cells. Based on measurements of the rate of stem cell turnover, the update of the radionuclide into the stem cell nucleus, and dose calculations for particular microdistributions, different modifying factors were defined and calculated in order to estimate the biological effect per unit intake. It was thus possible to compare the radiation effects of certain tritiated or I-125 labelled organic compounds with those from inorganic tritium or I-125 with a view to defining limits of intake.

- Although completely satisfying personal dosimeters for neutrons do not yet exist, progress has been made in developing the albedo dosimeter and nuclear track detectors. With new etching techniques it is now possible to make visible tracks of low energy recoil nuclei and alpha-particles.

- A small beta-dosimeter for measurement of dose at the surface of beta-sources has been developed, allowing precise dose evaluation for fingers, hands and forearms.

Behaviour and control of radionuclides in the environment

The main objective of the present programme is to acquire the necessary data to be introduced into the various models describing the transfer of radionuclides in the environment, used to estimate radiation detriment. Another aim is to find methods of estimating the possible damage caused to the environment and its components, together with methods of controlling it.

- Numerous results have been collected on the radiochemical, chemical, biological and oceanographical aspects of various radionuclides and on the transfer of associated pollutants in different marine ecosystems. Special attention has been given to the long-term behaviour of the transuranic elements, the possible synergistic effects of radionuclides and conventional pollutants (heat, chlorine compounds, etc.) and the behaviour of stable and radioactive isotopes. Mathematical models evaluating the cycling of chemicals in the marine environment have been considerably amended. These studies have improved the predictive capability needed for control of the areas surrounding reprocessing plants and in case of accidental releases.

- Research on radiocontamination of terrestrial and freshwater ecosystems was centred mainly on actinides but also on some important radioisotopes with long half-lives such as H-3, Tc-99, I-129, Pu-239 and Pu-240. A sensitive method for Pu determination in large soil samples is now available. Nevertheless many of the data at present available need to be improved in quality ; for instance, the observed modification of Pu transfer factors as a result of ageing must be quantified and explained. Initial observations on the properties of technetium have stressed both its mobility and its toxicity for living organisms.

- Research conducted on tritium has revealed that there might be an enhanced risk where the tritium is incorporated into living organisms before it becomes diluted into the environment.

- Work on I-129 is in progress and the extraction method developed is now applied to thyroid samples collected in selected areas of the Community.

- Studies on possibilities of decontaminating agricultural areas after an accident have been performed and several methods of decontamination were investigated. Application of chelating polyamine to soils already offers prospects of greatly reducing the soil plant transfer of some activation products.

Short-term somatic effects of ionizing radiation

The main objectives of the 1976-1980 programme in this sector are diagnosis and treatment of acute radiation injury.

- After total-body irradiation at relatively high dose, the stem cells of the hemopoietic system are the first to show severe damage. In man, these cells are present in the bone marrow. In principle, the transplantation of a certain amount of marrow from a healthy donor should cure the heavily irradiated individual. In practice however, experiments have shown that this procedure presents many difficulties which are progressively being overcome by a continuous research effort. For example, the donor and the acceptor need to be genetically as close as possible, otherwise the transplanted marrow reacts against the recipient and might even cause death. This is the so-called graft-versus-host reaction. The minimum number of bone marrow cells which is required for a complete recovery of the patient has now been established. Through extensive experimentation with human and monkey bone marrow cells, preservation of the regenerative capacity of these cells after storage can now be guaranteed. The minimum whole-body dose of radiation which will permit a "take" in given conditions has also been established. Several methods have been developed to prevent or treat the graft-versus-host reaction. Recently, progress has been made in the collection and use of hemopoietic stem cells from the peripheral blood.

- Considerable progress has also been achieved regarding the elucidation of damage induced in deoxyribonucleic acid (DNA) by ionizing radiation. Physical, chemical and biological techniques have been successfully applied to probe the major radiation-induced lesions in nucleic acids and their constituents. A broad knowledge has been gained about the sites and structural properties of free radicals as reactive species mediating the pathway to stable chemical alterations. The latter have been analysed in detail, thus providing a clue to alterations which are of importance in biological malfunctions. Biologically viable damage, such as base alterations and strand-breaks, has been well characterized in suitable model-systems.

Late somatic effects of ionizing radiation

In the current programme special attention is given to late somatic effects after acute or chronic irradiation or incorporation of radioisotopes. Studies are concentrated on irradiation levels in medical diagnostics and on those radioisotopes which are potentially among the most harmful, such as plutonium and the other actinides. Epidemiological studies of irradiated human groups with a view to formulating risk estimates in radiobiological protection are of great practical importance.

- EULEP has continued its effort on a successful coordination of research in the area of late somatic effects, with emphasis on standardization of experimental conditions in the laboratories involved in late effects research, on coordination of the planning of the corresponding cooperative research projects, on the execution of specific projects in the area of carcinogenic and non-carcinogenic late effects and on the radiotoxicity of incorporated radionuclides. Intercomparisons were performed in dosimetry, and first steps were taken towards standardization of laboratory animals. Semi-annual workshops on the pathology of radiation-induced lesions succeeded in standardizing terminology, especially on tumour classification. Results are published in the EULEP pathology atlas, an important source of reference.

- Also in the context of EULEP, a multidisciplinary research group has continued its coordinated investigation into the importance of vascular effects in the development of late radiation damage. Quantitative biological measurements in the cerebral cortex indicated that the gross vascular abnormalities are preceded by a significant increase in vascularity. These changes were not associated with any marked ultrastructural changes and therefore are considered as a primary effect of radiation. The slight increase in the total deoxyribonucleic acid (DNA) content of the brain over the same time period might indicate the increase in vascularity to be an active process.

- A chelating agent was shown to be effective in removing plutonium from the lung. Toxicity studies have shown that it is more toxic than other known agents like DTPA but a single injection may be sufficient treatment. The importance of this research is that it could lead to removal of intracellular plutonium. The clearance of plutonium nitrate from intramuscular retention sites has been measured.

- Am-241 is present in irradiated nuclear fuel. Realistic levels of permissible exposure to airborne Am-241 can only be set if adequate data on its retention and distribution within the body are available. The behaviour of Am-241 in nine men with long-standing burdens after accidental inhalation was investigated. This work was later extended to include studies of the comparative retention of $^{241}AmO_2$ and $^{238}PuO_2$ in the lungs of a subject more recently exposed. This study is of particular importance, not only because of interest in the lung clearance of PuO_2, but also because the detection of the 60-keV gamma rays from associated Am-241 is frequently used for determining pulmonary deposits of plutonium.

- Data on the various steps involved in the production of radiographs are important for the optimization of image quality (i.e. diagnostic value). Such data were obtained by spectrometric and dosimetric investigations of X-ray spectra and by determination of the spectral sensitivity of the various image-recording systems. The influence of different positioning, geometrical and exposure factors on the organ doses was estimated, in order to reduce the risk to the patient.

- A significant protection against late effect has been demonstrated in mice treated with a mixture of chemical protectors and then exposed to X-rays. The protection was effective mainly against thymic lymphoma, myeloid leukemia, sarcoma, glomerulosclerosis and non-cancerous lung lesions.

- Studies with a short-lived alpha-emitting osteotropic Ra-224 have shown that dose protraction by fractionated application results in a higher incidence of osteosarcoma (increasing with protraction time and total dose).

The highest osteosarcoma incidence of more than 90 percent was observed after a mean skeletal dose totalling 1080 rad over a period of 36 weeks. Other recent results have indicated that the bone tumour incidence after incorporation of a short-lived beta emitter (Lu-177) can also be enhanced if the dose is given in fractions over an extended period rather than in a single amount.

- The process of cancer induction by ionizing radiation is likely to be influenced by viruses. Comparative studies of various populations of viruses in radiation-induced leukemia were performed and two lines of splenotropic viruses have been isolated and characterized on a physico-chemical basis and identified as endogenous murine viruses. After incorporation of Ra-224 in mice, a transient expression of C-type RNA viruses immediately after the start of irradiation and a second type of virus expression during the time of tumour development (11 to 12 months after irradiation) have been observed in the skeleton.

- Synergistic effects between radiation and other environmental factors will have to be taken into account in risk evaluation because they may influence the biological radiation effects. Research was therefore recently begun on synergistic effects.
  One effect can be reported as example : the development of radiation-induced osteosarcoma seems to be accelerated by application during the latency period of cyclophosphamide, a widely used antimitotic agent.

- Epidemiological studies on patients treated with Thorotrast or Ra-224 are in progress. Preliminary results were achieved regarding risk coefficients for Ra-224. Further statistical analysis will still be necessary when all relevant data have been collected.

Genetic effects of ionizing radiation

The objectives, in this sector, aim essentially at the analysis in depth of the mechanisms governing the evolution of induced genetic lesions in irradiated cells and at establishing methods for assessing the nature and frequencies of cytogenetic damage in exposed individuals.

- Research on sensitivity and repair in experimental species, and particularly bacteria, yeast, and Tetrahymena greatly contributed to our understanding of the very complex ways through which the irradiated cell copes with its lesions. Many of the enzymatic and regulatory processes involved in repair, and among others "S.O.S." induction (an emergency syndrome which activates a complex metabolic pathway as a response to unrepaired DNA lesions and is probably involved both in mutagenesis and in malignant transformation of mammalian cells), have been identified and the major pathways for mutagenesis reconstituted.

- On the basis of results and clues obtained from research on micro-organisms, various biochemical techniques, gene localization methods, screening tests and procedures for prenatal diagnosis have been successfully developed for the purpose of detecting and specifying DNA repair defects in humans and thereby establishing a modern molecular approach to the protection of man against radiation. Among many significant achievements, the work carried out allowed the isolation and characterization of the first human mutant cells affected in post-replication repair and contributed to the revelation of the existence of the first human cell line abnormally sensitive to ionizing radiation. Various relationships of radiation sensitivity to sister chromatid exchange, mutagenesis and predisposition to cancer were established for certain repair deficient lines; for the disease Xeroderma pigmentosum seven genetically different forms were detected by means of complementation analyses. From research carried out on monkeys, the conclusion was reached that a dose of 850 rad severely affects the primate ovary and evidence was obtained which suggests the existence of inducible repair systems similar to the S.O.S. repair mechanism found in bacteria.

- In the area of radiocytogenetics, advances have been made with regard to our understanding of the mechanisms by which ionizing radiation produces chromosome aberrations and of the dependence of dose-effect relations on radiation quality and different sets of experimental conditions. Evidence has been obtained, through an analysis of mutation incidence at 13 X-chromosome loci in Drosophila, which suggests proportionality between spontaneous and induced mutation rates. The dose-response relationship after X-irradiation has been established for anomalies in the distribution of sex-chromosome in mammalian germ-cells. Successful approaches towards the analysis of radiation effects on human meiosis were carried out in two different directions, through the development of culture techniques and by three-dimensional reconstructions of human nuclei from electron micrographs.

Evaluation of radiation risks

The perception and evaluation of the "radiation risk" have evolved to such an extent that it has become necessary to analyse thoroughly all its aspects. Work has been initiated in this direction during the present programme, with the intention of determining the optimal conditions for the implementation of nuclear energy. Therefore, research was started on the economic and social consequences of irradiation, on the assessment of the radiological detriment, i.e. the global deleterious effects for a population which could arise from radiological exposure, and on the assessment of the individual and collective doses in respect of normal discharges of nuclear power installations and in the event of an accident.

- Values are now available concerning certain parameters to be used for the assessment of the collective dose. In particular, a long-distance atmospheric dispersion model (MESOS model) has been developed which enables the atmospheric contamination to be evaluated on the basis of gaseous effluents at intermediate distances. In addition, mapping of the geographical distribution of the populations in the nine Community countries has been completed and is based on a programme which provides data relating to the population distribution for a unit grid mesh of 10 km x 10 km. It should be noted that this work, which was carried out with the aim of obtaining an accurate idea of the collective dose received by the European population, can also be used for many other purposes. Moreover, a model of the dispersal of contaminated products associated with the distribution and marketing networks has been compiled for marine products in France. It can be applied to the other Community countries.

- As regards the attempts to assess the radiological detriment, a great many studies, both bibliographical and experimental are at very advanced stage; however a new line of thought emerges from the epidemiological studies concerning individuals that have been irradiated either as part of medical treatment or as a consequence of their occupational activity. In the latter case, a feasibility study has been initiated on the preparation of a European irradiation register for workers directly assigned to tasks in which they are exposed to irradiation.

- As regards the application of methods for evaluating the economic and social consequences of irradiation, research has been directed towards the

determination of levels that are "as low as reasonably achievable" (ALARA). Various methods, by which radiation protection can be optimized, have been indexed in such a way as to highlight their respective advantages and disadvantages. First of all, the multicriteria method was applied for a selected objective (fuel cycle for a programme of 100 1-GWe PWR reactors); this method, which requires a certain amount of weighting in relation to the various criteria on the basis of which it is intended to assess the options, brings out the variability of the choice of options (in other words the "ALARA" levels) in the light of the priorities put forward by the decision-makers.

*

* *

This selection of results from current projects in the Radiation Protection Programme clearly shows that definite results have been achieved in several areas, which to a large extent are already of significance as regards practical application. Simultaneously, it can be seen that there are many interim results which require further intensive work; it is precisely these which will be of considerable value in the coming months and years. Part of the research programme is on a long-term basis, and results can only be expected in a more distant future. It is anticipated that this work will, in particular, provide basic data on the radiation effects of low and very low doses, which is an extremely important radiation protection problem.

Finally, it should be mentioned, that the results of research in the field of radiation protection often have effects extending into other, related fields. The example of bone-marrow transplantation is typical of the close relations between radiation protection and medical therapy. This complex method, being developed for treatment of severe radiation accidents is presently attempted for clinical treatment of leukemia.

APPENDIX II

PROPOSAL FOR A COUNCIL DECISION ADOPTING A FIVE-YEAR RESEARCH AND TRAINING PROGRAMME (1980-1984) OF THE EUROPEAN ATOMIC ENERGY COMMUNITY IN THE FIELD OF BIOLOGY - HEALTH PROTECTION (RADIATION PROTECTION PROGRAMME)

The Council of the European Communities,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 7 thereof,

Having regard to the proposal from the Commission, submitted after consulting the Scientific and Technical Committee

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas it is in the interest of the Community to supplement, broaden and deepen the information necessary for an objective evaluation of the effects of and the hazards arising from ionizing radiation in order to guarantee an adequate protection of man and the environment,

Whereas a scientific collaboration, exchange of information and mobility or interchange of scientists at Community level is a necessity in radiation protection,

Whereas the progress of knowledge, the new concepts in radiation protection and the need for managerial improvement call for the replacement of the present 1976-1980 programme by a new 1980-1984 programme, with 1980 as an overlapping year; whereas Council Decision 76/309/Euratom[1] should therefore be repealed;

Whereas the research dealt with by this Decision is an appropriate way of pursuing such action, and it is therefore in the common interest to adopt a multiannual programme in the field of radiation protection,

[1] OJ No L74, 20.3.76, p.32

HAS DECIDED AS FOLLOWS :

Article 1

A research and training programme in the field of radiation protection as defined in the Annex is hereby adopted for a five-year period beginning 1 January 1980.

Article 2

The total amount required for the duration of the programme is estimated at 68.2 million EUA, as defined in Article 10 of the Financial Regulation of 21 December 1977, and the staff allocation at 64 persons. These figures are merely intended as a guide.

Article 3

Decision 76/309/Euratom is repealed with effect from 1 January 1980.

Done at Brussels,

For the Council

The President

ANNEX

RADIATION PROTECTION PROGRAMME

(indirect action)

The aim of the programme is, through a co-operative European effort, to increase knowledge in radiation protection while taking into account particular problems and skills available in Europe. It is designed to gain adequate understanding and control of the radiation risks encountered, with two main objectives :

- improvement of scientific and technical knowledge with a view of updating basic standards for the health protection of general public and workers against the hazards arising from ionizing radiation ;
- evaluation of the biological and ecological consequences of nuclear activities and of the use of nuclear energy and ionizing radiation, in order to ensure an adequate protection of man and of the environment whenever unacceptable harm could otherwise be caused to them.

The programme will consist of six major areas. They are :

- radiation dosimetry and its interpretation,
- behaviour and control of radionuclides in the environment,
- short-term somatic effects of ionizing radiation,
- late somatic effects of ionizing radiation,
- genetic effects of ionizing radiation,
- evaluation of radiation hazards.

The activities shall be carried out mainly under research contracts and partly by the Commission's Biology Group at the Ispra Establishment of the Joint Research Center.

APPENDIX III

Opinion of the Advisory Committee on Programme Management "Radiation Protection" on a proposal of the Commission for a Research and Training Programme (1980-1984) for the European Atomic Energy Community in the field of Biology-Health Protection (Radiation Protection Programme)

During its meetings of 17 October 1978 and 13/14 November 1978, the Advisory Committee on Programme Management "Radiation Protection" has examined in detail the proposal of the Commission for a Research and Training Programme (1980-1984) for the European Atomic Energy Community in the field of Biology-Health Protection (Radiation Protection Programme), and in particular the steps taken to assure coordination between national and Community activities in this field.

The ACPM stated unanimously that it is in the interests of the Community to supplement, broaden and deepen the information necessary for an objective evaluation of the effects of and the hazards arising from ionizing radiations in order to guarantee an adequate protection of man and the environment.

The ACPM agreed unanimously that the scientific content of the proposal is based on a sound assessment of the current and foreseeable research requirements of the Community in radiation protection.

The ACPM proposed unanimously to agree on a renewed multiannual programme as an appropriate way of pursuing research in radiation protection.

J.W. HARMAN
President of the ACPM

Opinion of the

Scientific and Technical Committee of 19 January 1979

on the

Proposal for a "BIOLOGY-HEALTH PROTECTION, Radiation Protection" Programme for 1980-84

The Scientific and Technical Committee, at the meeting of 19 January 1979, examinated the draft proposal for a "Research and Training Programme (1980-1984) for the European Atomic Energy Community in the field of Biology-Health Protection (Radiation Protection Programme)", to be submitted to the Council by the Commission.

The S.T.C. endorses the view already expressed by the A.C.P.M. namely that "it is in the interest of the Community to supplement, broaden and deepen the information necessary for an objective evaluation of the effects of and the hazards arising from ionizing radiations in order to guarantee an adequate protection of man and the environment".

The S.T.C. also noted that the scientific and technical information arising from this programme will assist significantly in updating basic radiation protection standards.

The S.T.C. very strongly supports the proposal of the Commission to implement an overlapping programme for both scientific and organizational reasons and expresses a favorable opinion on the proposed programme.

FINANCIAL RECORD

BIOLOGY AND HEALTH PROTECTION

RADIATION PROTECTION PROGRAMME

1. RELEVANT BUDGET HEADING

- Item: 3352

- Title: Biology and health protection (radiation protection)

1.1 TITLE OF THE PROJECT

Biology and health protection

Radiation protection

2. LEGAL BASIS

- Application of Article 1 of the Treaty establishing the EAEC and Annex 1 thereof;

- Council Decision of .....

3. DESCRIPTION OF THE PROJECT

3.1 Description

Continuation of a coordinated research programme on radiation protection, implemented in particular through shared-cost contracts.

3.2 Objective

Study and assessment of the dangers arising from ionizing radiation, under two main tasks:

- improvement of scientific and technical knowledge, in order to update the Basic Safety Standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation;

- assessment of the biological and ecological consequences of nuclear activities and of the use of nuclear energy and ionizing radiation, in order to provide sufficient protection of man and the environment in the event of exposure to unacceptable hazards.

4. JUSTIFICATION OF THE PROJECT

This project comes under three policies whose importance is at present undisputed:

- social affairs
- the environment
- energy.

5. FINANCIAL IMPLICATIONS OF THE PROJECT IN RESPECT OF EXPENDITURE (including staff expenditure and administrative and technical operating expenditure)

5.1 Overall cost for the whole of its expected duration: 143 210 000 EUA

5.2 Chargeable to the Community Budget: 68 210 000 EUA

Chargeable to national budgets: } 75 000 000 EUA

Chargeable to other sectors at national level: }

5.3 MULTIANNUAL TIMETABLE

5.3.1.1 APPROPRIATIONS FOR COMMITMENT (EUA)

	1980 Old prog.	1980 New prog.	1981	1982	1983	1984	1985
Staff	3.583.000	-	3.797.000	4.025.000	4.267.000	4.526.000	-
Admin. and tech. operation	579.000	-	615.000	650.000	689.000	731.000	-
Contracts	(5.848.000) [1]	15.000.000 [2]	16.000.000	5.000.000	2.900.000	-	-
Total	4.162.000* (+5.848.000) (10.010.000)	15.000.000	20.412.000	9.675.000	7.856.000	5.257.000	-
		= 58.200.000					

5.3.1.2 APPROPRIATIONS FOR PAYMENT (EUA)

	1980 Old prog.	1980 New prog.	1981	1982	1983	1984	1985
Staff	3.583.000	-	3.797.000	4.025.000	4.267.000	4.526.000	-
Admin. and tech. operation	579.000	-	615.000	650.000	689.000	731.000	-
Contracts	4.100.000	-	6.900.000 (1.756.000) [3]	9.150.000	9.750.000	10.400.000	2.700.000
Total	8.262.000	-	11.312.000 [4]	13.825.000	14.706.000	15.657.000	2.700.000
		= 58.200.000					

[1] The amount of 5 848 000 EUA is the Community's financial contribution to the contracts in 1980, covered by previous commitments which are still outstanding and appropriations for commitment remaining from the old programme.

[2] The appropriations for commitment amounting to 15 000 000 EUA will enable contracts with an earliest starting date of 1 January 1981 to be prepared, committed and signed in 1980.

[3] This figure represents appropriations for payment from the old programme.

[4] 11 312 000 EUA in appropriations for payment from the new programme
+ 1 756 000 EUA in appropriations for payment from the old programme

13 068 000 EUA

*4 045 000 EUA of which to be covered by appropriations for the old programme which have not yet been included in the budget and 117 000 EUA of which to be covered by remaining appropriations for commitment.

5.3.2 Method of calculation

In estimating expenditure for the years 1981-84, a rate of increase of 6% has been assumed.

(a) Staff expenditure

Staffing needs have been calculated on the basis of a staff of 64 for the programme: 41 Category A staff;
12 Category B staff;
10 Category C staff;
1 Category D staff.

The total staff of 64 and the breakdown into grades corresponds to the staffing situation in the 1979 Budget.

(b) Administrative and/or technical operating expenditure

This heading covers expenditure connected with missions and the organization of meetings, the technical operating expenditure of the Ispra Biology Group and the use of the scientific and technical support of the JRC's Ispra Establishment.

(c) Contract expenditure

Since the type of subject and the contractors' qualifications vary, it is not possible to establish a uniform method of calculation. However, an average contribution of 40% to the contractual partners' total costs has been taken as a basis for the estimate. At all events the Advisory Committee on Programme Management will be consulted when the amount of Community participation is finally determined.

6. FINANCIAL IMPLICATIONS ON THE STAFF AND NORMAL OPERATING APPROPRIATIONS

(See under paragraph 5 above)

7. FINANCING

Appropriations to be entered under future budgets.

8. FINANCIAL IMPLICATIONS OF THE PROJECT IN RESPECT OF REVENUE

- Community tax on officials' salaries.

Officials' contributions to the pension scheme.

9. TYPE OF CONTROL TO BE APPLIED

- Scientific control by the Associations Management Committee, the Advisory Committee on Programme Management (ACPM) and the responsible officials in DG XII.

- Administrative control by the Directorate-General for Financial Control with regard to the implementation of the Budget and to check that the expenditure is in order and conforms to the relevant provisions; and by the Contracts Department of DG XII.