

STERILISATION OF TISSUES USING IONISING RADIATIONS UNDER REVIEW

In association with the International Atomic Energy Agency, an International High Level Expert Meeting on the Use of Ionising Radiation for Tissue Sterilization will be held in Wrexham, North Wales, U.K. from September 1-5, 2003 following a recommendation adopted by the IAEA Technical Advisory Committee in its Second Meeting held in Vienna, Austria in December last year. The **Cellucon** Trust, a Charitable Educational Trust under U.K. Law, will support the organisation of the meeting, in cooperation with North East Wales Institute of Higher Education (NEWI).

Title: STERILISATION OF TISSUES USING IONISING RADIATIONS

Background:

The use of ionising radiation for sterilization/decontamination of tissues was one of the main topics discussed in the last meetings of the American Association of Tissue Banking (AATB), the Asia-Pacific Surgical Association of Tissue Banks (APSATB), and the European Association of Tissue Banking (EATB), held in August, September and October 2002 respectively. The IAEA Technical Advisory Committee also discussed this topic in its Second Meeting and agreed on the IAEA proposal to call an international high-level expert meeting on the use of ionising radiation for tissue sterilization, to be held from 1 to 5 September 2003 in Wales, United Kingdom, under the IAEA Radiation and Tissue Banking Programme. The Committee welcome this IAEA initiative due to the importance of this subject for the tissue banking community.

During the debate of this important subject two viewpoints, with different degrees of emphasis, were clearly identified. One view was that the use of the ionising radiation for the sterilization/decontamination of tissues, either in the initial or the final stage of a defined processing method, was necessary. The second view was that the use of ionising radiation for the sterilization/decontamination of tissues makes it unsuitable for certain medical use.

The IAEA followed very carefully the debate of this important subject within the different Tissue Banks Professional Association meetings, and taking into account its international responsibilities and experience in the use of the ionising radiation for sterilization/decontamination of medical products, pharmaceuticals and tissues over the last 30 years, decided to organize an international high-level expert meeting for the debate of this topic within the tissue banking community. The objective is to establish the best conditions for the use of ionising radiation to sterilize tissues, and to disseminate and **update** this information to the IAEA Radiation and Tissue Banking Program and the wider tissue banking community.

It was recognized that existing methods and processing for sterilising tissues are proving, in many instances inadequate. Infections have been transmitted from the graft to the recipient and in the USA, the Centre for Disease Control and other regulatory bodies have drawn attention to the need for a reliable end sterilisation method, which does not damage the functionality of the final tissue.

Guidance from the International Tissue Bank Professional Associations: The Presidents of the American, European, and Latin America Professional Associations of Tissue Banks met in Vienna in a meeting of the IAEA Technical Advisory Committee to review the situation and concluded that the time was opportune to organise an international high level expert meeting, which would identify the best method of using radiation technology to assist in the production of safe tissue allografts and welcome the IAEA proposal.

SUBJECT AREAS TO BE COVERED AT THE MEETING

A - Setting the Scene. The IAEA Program on Radiation and Tissue Banking and the Need for Irradiation of Tissues

- Introduction to IAEA Program on Radiation and Tissue Banking
- The need **for irradiation** of tissue in relation to contamination in existing practices
- Radiation sources: types and suitability for tissues; dosimetry, taking into account size, variability, density, low temperatures of tissues and quality systems.

B - Consideration of the radiation dose levels needed to inactivate possible contaminating microorganisms in recovered tissue.

Inactivation of microorganism in tissues

Current situation:

Processes and practices leading to bacterial (biological) inactivation in tissues.

Practical problems:

- Protective effect of the tissues, water content, oxygen tension, temperature effects, radiation resistant organisms
- Viruses and Prions
- Potential for pre-processing (decontamination) and final package sterilization

C - Effects of radiation on the integrity and functionality of tissues

1 – BONE:

Current situation:

Clinical experience with structural and non-structural bone grafts

Practical problems:

- Chemical change in components: collagen, bone morphogenic protein, glycosaminoglycans, role of free radicals in tissues
- Biomechanical effects of radiation. Research and clinical finding
- Demineralised and other relevant bone: osteoinductive changes, clinical relevance

2 - SOFT TISSUES:

Current situation:

- Tendon, vessels and heart valves: changes with increasing dose/dose limits
- Amnion and skin

Practical problems:

- Tendon- reduced function with dose
- Irradiation in glycerol systems
- Irradiated allodermis as **a bed** for cultured grafts

D - IAEA Code of Practice for the Radiation Sterilization of Tissues Allografts.

IAEA Code of Practice for the Radiation Sterilization of Tissues Allografts

Current situation:

- The draft IAEA Code of Practice
- Regulatory system as factor in influencing policy.
- ISO approach to tissues

Practical problems:

- Bioburden measurement
- Viral contamination
- Validation in relation with Standards

Structure of the report to be presented

For each of the major topics to be discussed in the meeting a report will be prepared by a leading expert in the field. The structure of the report to be prepared is the following:

- 1 - The problem or problems to be addressed.
- 2 - How this problem (or problems) is (are) affecting the work in the tissue bank?
- 3 - Possible solutions to be adopted or actions to be considered
- 4 - Recommended actions to be considered or solutions to be adopted

Organisation

The Location of the Meeting

The meeting will be held in the North East Wales Institute of Higher Education (NEWI) which is situated in the small town of Wrexham situated in North Wales on the Welsh border with England, and 10 miles from the city of Chester. Wales is a separate country from England, having its own language and culture. North Wales is a holiday area, which attracts lovers of coast and countryside in equal measure. It is a varied region, with long stretches of sands, craggy mountain, towering headlands and deep valleys. Snowdon, the highest peak in Britain, south of the Scottish Highlands dominates a rocky mass of mountains, which acts as a magnet to climbers and walkers. To the east in **contrast is** a much gentler landscape of heather moorlands, green **valleys** and the rounded hills of Wales border country.

Living Accommodation

On the NEWI campus there is a Student Village, which has **en-suite** bedrooms and is being regularly used by other conferences. Its use reduces costs compared with hotels. All meals will be arranged on-site and a Welsh Banquet on the final evening. A special outing to the Medieval Banquet at a local old Welsh Castle can be arranged at an individual charge for delegates wishing to go. The Cellucon Trust will sponsor a social evening involving a Welsh Male Voice Choir. The facilities provide excellent opportunities for informal meetings and discussion

Costs to Meeting Delegates

Accommodation cost will be £75 per day, which will include a single room in the student village for one night, breakfast, lunch and dinner. For participants who wish to join the meeting the conference fee is £150 sterling. IAEA will be able to provide some support for Experts who are invited to contribute to the programme, but since resources of necessity are limited, this will need to be considered on an individual basis. Organisations are asked to support the meeting by contributing to the costs of delegates.

Applications and Replies

All communication should be to:

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