

# Research Involving Radiation Exposure of Human Volunteers

**The purpose of this information bulletin is to explain the requirements of the Health (Radiation Safety) Regulations 1994 which apply to Research Involving Radiation Exposure of Human Volunteers.**

## Introduction

The *Health Act 1958* and *Health (Radiation Safety) Regulations 1994* control all uses of ionising radiation in Victoria, and include a system requiring the licensing of operators of radiation equipment and radioactive sources, and the registration of irradiating apparatus and sealed radioactive sources. There are specific licensing requirements related to research projects involving irradiation of human volunteers.

## Licensing

Administration of ionising radiation to human volunteers requires a valid licence issued by the Department of Human Services (DHS). Prior to commencement of any research project involving the exposure to ionising radiation, the research institution must apply to DHS for a *Company/Institution licence* for research with human volunteers if it does not already have one.

Any research projects where participants do not receive a direct medical benefit or where radiation received by a patient is not part of normal clinical treatment is required to be recorded on the Institution's licence

Any person who administers ionising radiation is required to hold an *operator licence*.

## New Approval Process

A new model of approval of research projects involving irradiation of human volunteers has been implemented in Victoria.

In the past, the Radiation Safety Program of DHS with advice from the Radiation Advisory Committee has effectively been reviewing research proposals to determine the radiological justification.

In May 2005, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) published the new **Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes (2005)** (available at <http://www.arpansa.gov.au/>). The Code establishes the preferred regulatory requirements for the approval of research projects.

Compliance with the new Code will become a condition of licence for research projects involving irradiation of human volunteers.

The adoption of the new Code will introduce substantial changes to the way research involving ionising radiation on human volunteers is approved in Victoria. There will be a trial period of approximately 12 months for implementation of this new procedure

In this new model the Human Research and Ethics Committee (HREC) of the institution performing the research is required to assess the research submission in accordance with the new Code. The HREC is required to assess the balance between the likely benefits and risks associated with the radiation exposure taking into account Annex 1 of the Code, 'Assessment of Risk Associated with the Radiation Exposure'.

Only research projects *where the radiation dose exceeds the constraints listed in Table 1 of the Code and where the participant receives no direct benefit* should be sent to the RSP for review and approval. This implies that research involving patients who may receive a dose greater than the dose

constraint but may also receive a direct benefit, eg some cancer trials, would *not* have to be referred to the RSP for review.

The Code requires the researcher to obtain a written assessment from an independent medical physicist of the total effective radiation dose that the participant is likely to receive as a result of being part of the research. *This does not include any exposure that would form part of routine treatment.* The dose assessment would help the HREC to determine whether the radiological component is justified based on the information in the Code.

The Code defines a medical physicist as a person qualified to perform the necessary dosimetric calculation and who has been approved by the regulatory authority. This Department is currently in the process of preparing a list of 'approved' medical physicists which will be available shortly.

Once the project has been reviewed and *fully approved* by the HREC the RSP is required to be notified in writing so that the project can be added to the Institution's licence.

Notification must include project title, a brief summary of the purpose of the project, name of the principal researcher, location where the research will be conducted, radiation dose to the participant, type of radiological procedure, name of medical physicist who performed the dose assessment and a copy of the dose assessment.

The HREC is also required to notify the RSP in writing when the project has finished so that it can be removed from the licence.

### **Summary of requirements for approval of research projects involving irradiation of human volunteers.**

1. The HREC to review the radiation component of the research project in accordance with the new Code.
2. Independent advice from a medical physicist is required by the researcher regarding the radiation dose to the participant, from participation in the research.
3. If the dose to the participant exceeds the dose constraint in Code, and the participant receives *no direct* benefit, then the research project will be required to be reviewed by the RSP (as per the current system).
4. As soon as the project is *fully approved* by the HREC, the RSP is required to be notified in writing. The notification must include the information listed above.

You are encouraged to make any comments or suggestions to the Radiation Safety Program in writing to help improve the new arrangements.

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## **References**

Radiation Protection Series No. 8 *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)* ARPANSA

ICRP, 1991, *1990 Recommendations of the International Commission on Radiological Protection*, Publication 60 (Annals of the ICRP VOL.21 No. 1-3), Pergamon Press.

Radiation Protection Series No. 1 *Recommendations for Limiting Exposure to Ionising Radiation* (Printed 1995 - Republished 2002) and *National Standard for Limiting Occupational Exposure to Ionising Radiation* (Printed 1995 - Republished 2002) ARPANSA

## **Further Information**

For further information please contact:

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### **Medical Radiation Technologists Board**

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