AUTHENTICITY, RADIOCHEMICAL PURITY AND SPECIFIC ACTIVITY OF SUPPLIED RADIOCHEMICALS PRIOR TO ADMINISTRATION TO ANIMALS AND/OR MAN

1. GENERAL

For handling radioactive substances, see SOP/TSB/020.

2. INTRODUCTION

Radiochemicals are received by IRI according to SOP/TSB/020. Prior to initiation of any metabolic study in animals in general and man in particular, the authenticity, radiochemical purity and specific activity of the material must be substantiated at IRI, whether this information has been supplied or not.

3. AUTHENTICITY

The radiochemical is assayed by comparative chromatographic techniques against supplied authentic reference material. Authentic reference material should be requested in the materials section of the experimental protocol. Chromatographic techniques e.g. thin-layer chromatography, gas liquid chromatography, high performance liquid chromatography or gas chromatography-mass spectrometry are used as considered appropriate.

4. RADIOCHEMICAL PURITY

Radiochemical purity is determined in two chromatographic systems (generally two TLC systems). The purity of compounds for use in animals should be greater than 97% in both systems. In man, attempts should be made to work with material of greater than 99% radiochemical purity. Materials outside these limits are generally re-purified prior to use: but in exceptional circumstances and with agreement between the IRI Principal Investigators and the Sponsor, lower radiochemical purity may be accepted.
4.1 **Thin-Layer Chromatography (TLC)**

Two TLC systems which advance the authentic compound to \( R_f \approx 0.4 - 0.7 \) are used.

The authentic compound, the radioactive compound and an intimate mixture of the two are run on the same TLC plate (Merck Kieselgel 60 F\textsubscript{254} of layer thickness 0.25 mm). Following development of the chromatogram through 10 or 15 cm, the TLC plate is dried and the non-radioactive areas visualised by:

a) quenching of fluorescence at 254 nm, or
b) iodine vapour

The radioactive areas are visualised by:

i) thin-layer chromatographic scanner, or
ii) autoradiography (SOP/MET/350)

Following comparison of non-radioactive with radioactive areas, the proportion of authentic radioactive compound (purity) is estimated by excision of silica gel and scintillation counting (SOP/MET/310).

4.2 **High Performance Liquid Chromatography (HPLC)**

Under some conditions, it may be considered appropriate to use HPLC in which case, HPLC systems are sought which separate reference compounds of similar structure. The unlabelled authentic compound may be "visualised" by fluorescence or by UV or colorimetric techniques and the radioactive component by:

a) Berthold HPLC radioactivity monitor
or
b) fraction collection and scintillation counting (SOP/MET/310).