

ACPSEM / ANZSNM SIG Workshop 2004

Challenges to Regulatory Agencies With Emerging Technologies

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Challenges to Regulatory Agencies With Emerging Technologies - Medical

- A previously unidentified need has emerged.
- Two modalities with differing requirements become merged.
- Previous modality gains new uses.



Some case studies

- **Intra-vascular Brachytherapy**
 - **Cardiac procedure for the treatment of restinosis.**
 - **Cardiologists do not have licence condition allowing them to use therapeutic radioactive sources.**
 - **Restinosis is not cancer, therefore, oncologists not qualified?**



Some case studies

- **Intra-vascular Brachytherapy**
 - **Solution:** After consultation with other states, RAC, international practice, allow interventional cardiologists to perform treatment under the supervision of brachytherapy rep (first 3 procedures only), therapy medical physicist and oncologist.



Some case studies

- **PET/CT or SPECT/CT**
 - **Nuclear medicine procedure utilising nuclear medicine and diagnostic radiography equipment.**
 - **Problems:**
 - **Few if any technologists trained as both radiographer and nuclear medicine technologist.**



Some case studies

- **PET/CT or SPECT/CT**
 - **Problems (cont):**
 - **Suitable training course still year away when first PET/CT delivered to hospital.**
 - **Solution: Temporary licence condition created granted to NMT's that have received proper in-house training.**



Some case studies

- **Cyclotron**
 - **Radiation apparatus used to produce radioactive substances.**
 - **Problems:**
 - **Classed as an apparatus or a substance?**
 - **What registration criteria?**
 - **What licensing criteria for operators and maintainers?**



Some case studies

- **Cyclotron**
 - **Solutions:**
 - **International guidance.**
 - **12 month forewarning.**
 - **Keen staff.**
 - **Substance and apparatus condition issued to operators. apparatus licence issued to installer / maintenance.**



Some case studies

- **Whole-body CTs**
 - **CT technology around since 70's, and ever improving.**
 - **Late 90s, multi-slice technology had improved to the point where a number of maladies could be imaged, with a relatively low exposure rate.**



Some case studies

- **Whole-body CTs (cont)**
 - **Problem:**
 - **With this new technology, advent of entrepreneurial medicine scheme.**
 - **In Australia, procedure not covered by MediCare or private insurance providers, so “patients” cover costs.**



Some case studies

- **Whole-body CTs (cont)**
 - **Problem:**
 - **Possibility that CT performed for non-diagnostic procedure could identify non-problems, or not-important-problems.**
 - **After investigation, evident that CT providers were not giving sufficient risk information to clients.**



Some case studies

- **Whole-body CTs (cont)**
 - **Solution:**
 - **Licence condition changed for all radiographers and radiologists instructing that persons receiving whole-body procedures receive minimum risk instructions, and that the procedure is referred by independent practitioner.**



Questions?

