

Implementation of the ICRP-60 Recommendations by Swiss Pharmaceutical Companies



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1. Introduction

In 1994 the new Swiss Legislation on Radiological Protection that was based on the ICRP-60 was put into force

- reducing the annual dose limits for occupationally exposed persons from 50 mSv to 20 mSv
- new activity limits for the classification of controlled areas, new exemption limits and new guideline limits for contamination

2. Impact of the ICRP-60 on Swiss pharmaceutical and agribusiness companies

- No problem with the new dose limits as the doses had been far below 20 mSv already before 1994
- Reclassification of some isotope laboratories
- Slight changes in waste management and dosimetry

3. Implementation of the ICRP

- All local rules had to be rewritten in order to keep a consistent framework
- Risk analyses had to be written for laboratories in which more than 10 GBq ³H or 90 MBq ¹⁴C were handled per day
- Based on the results of the risk analyses new safety regulations had to be introduced
- Training of all radiation workers in using the new SI-units and limits
- Some of these tasks were accomplished by Novartis, Syngenta and Roche together. This led to harmonization of radiation protection among these three companies, mainly in training programs, contingency plans and check lists

4. Comparison with the EU directive and the German ordinance for radiation protection

- 1996: EU Directive for the Protection of Health of Workers and the General Public against the Dangers Arising from Ionising Radiation
- 2002: New German Radiation Protection and X-Ray Protection Ordinances put into force

Although the European Directive and the German Ordinances are based on the ICRP-60, too, there are important differences between the Swiss and German legislation.

5. Critical appreciation of the implementation of the ICRP-60

- **No health benefit** for occupational exposed persons as the radiation doses had been low before
- **No harmonization** between the Swiss and German legislation in radiation protection
- **No harmonization** between the legislation in radiation protection and the legislation of transportation of radioactive goods
- **Costs** for rewriting and implementing the new local rules.

The benefit/cost-analysis of implementing the ICRP-60 seems to be rather poor.

- **Benefit:** Common criteria of Roche, Syngenta and Roche for risk analyses and alarm thresholds

6. Advices for pharmaceutical and agribusiness companies in the EU

The costs for implementing the new legislation are high compared with the benefits. The costs can be reduced by:

- **Early planning of cooperation among the companies, especially within the same branch.** In Germany for instance the chemical industry association VCI has established a working group where radiation safety experts of chemical and pharmaceutical companies find a platform to discuss their local rules and training programs in radiation safety for standardisation purposes. But also some initiatives in Germany have been started to coordinate and synchronize local radiation safety rules among different industrial branches. An example is a “working group industrial radiation safety” where radiation safety experts of some blue chips companies share their experiences in radiation safety and develop archetypical local rules. Last not least local initiatives to coordinate local radiation safety rules have been started between companies operating in several industrial parks in Germany
- **Forming a common delegation for negotiating with the authorities**
- **Early contacting the HSE officers in all companies**
- **Waiting as long as legally possible** before starting the rewriting and implementing of local rules. Most important, wait until the Government has enacted all relevant ordinances and directives and until there are no doubts left how these directives have to be interpreted. If requirements are not clear, useless or too expensive, the common delegation should negotiate with the authorities.