HERCA: Heads of the European Radiological protection Competent Authorities

Regulatory framework and inspections in Eastern Europe

HERCA WGMA Inspector Workskshop 2015
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Petr Papírník
State Office for Nuclear Safety (Czech Republic)

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The Regulatory Body is truly independent – it reports DIRECTLY to Government

CZ: yes – advice: this is the most important; best is to have the independent chairmen on politics – best with long period of service which is independent on election periods (the more noticeable and respected person the better)

SK: the regulation is split between several under-departments of several ministries

It has the power to make legislation and to issue guidance

CZ: yes

It is a single body with regional offices (for greater efficiency) but follows a consistent set of philosophies and procedures

CZ: yes – one central directorate, the regional centers as its subdivisions

It is adequately resourced: CZ yes

has well-developed IT systems: CZ not so perfect

stakeholder engagement: CZ we are working on it, but far from perfect world – we have scientific support organization (for RT and RDG/IR, missing for NM), groups of experts in RT and RDG/IR (missing for NM), we recently set a very good cooperation with Ministry of Health

but our cooperation with professional organizations is occasional and we have almost no cooperation with the regulatory body for medical devices

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The Regulatory Body is responsible for all ionising radiation exposures

medical, occupational, public

CZ: yes (in medical we share the responsibility with Ministry of Health, but we as well as the Ministry have almost all the competencies in it – the share causes no problems)

The Regulatory Body is responsible for all sectors

nuclear, industrial, medical

CZ: yes (in medical we share the responsibility with Ministry of Health, but we as well as the Ministry have almost all the competencies in it - the share causes no problems)

Its activities are supported by a clear and appropriate regulatory framework and comprehensive enforcement options

CZ: yes – our new legislation will be a lot clearer, but even though we haven't had any problems with a weak legislation yet.

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The Regulatory Body provides a comprehensive range of activities including

authorisation and licensing: CZ: yes

inspection CZ: yes

We authorize / license and inspect: users of sources for MA (advice don't let the Ministry of Health prohibit your inspectors look into patient's documentation – one of the biggest problems, by the strict law we aren't allowed to look at any patient's data – we can't se pictures and judge collimation, we can't see and judge referring, …)

We authorize / license and inspect: providers of QC tests (annually tests) (advice – very good choice to have them under your wings) and dosimetry services

We participate on authorization of providers of external clinical audit, but we don't inspect them: advice: keep both under your wings completely

We don't authorize nor inspect radiological physicists (I don't see it necessary)

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The Regulatory Body undertakes authorisation, licensing and inspection following a graded approach CZ: not perfectly but it'll change with new legislation

we will have registration for dental

the inspection plan will focus more on the more important practices

now our inspections in hospitals are undertaking all the X-ray use in MA with graded approach focused more on the more important practices but the more graded approach we will apply the better

with a well-developed single IT portal for stakeholders CZ: not perfect – we want to change it but still this is a perspective too far

The groups responsible for these activities interact on a regular basis and provide input into each other's work CZ: yes – we have special inspection group for RT and RDG (missing for NM) and special group for evaluating and judging prosecutions for bad inspections and special group for authorization of external clinical audits. The cooperation between these groups could be better, but is not bad.

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The Regulatory Body is adequately staffed with professionals from each of the sectors

- for medical, this includes doctors, physicists and radiographers CZ: this idea is important, great, but one of the hardest we are staffed like this more or less exceptionally (from about 30 inspectors for MA we have about 10 people like this: 2 doctors, 2 physicists, rest radiographers)

There is a strategic plan including staff and other resources CZ: not

In small countries a strategic plan including staff is very hard to realize – there are too few people with adequate education and experience, so we focus more on developing potential individuals

Other resources??

There are comprehensive training packages in place – for induction and continuing professional development CZ: yes / no – formally it is set and working, but still it is very formal and if focused on the real practice, than on the clerk not on the clinical point of view. But we are working on it and hopefully getting better

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The Regulatory Body undertakes a range of inspections as appropriate

pre-licensing CZ: no – it would be great, but we have almost no law for this – the licensee gets under our wings only after licensing

proactive (as part of a programme) CZ: yes – the base of our work – inspections once in some time that is set by graded approach

and reactive CZ: occasionally, exceptionally – if we have some information about some bad practice or some announcement, or within one year after inspection that led to prosecution

announced CZ: most of the inspections (regular)

and unannounced CZ: very exceptional (I think that we haven't used it yet, but we can)

The inspection programme follows a risk based approach and is informed by previous experience CZ: yes – (regularly 1 x 2 years in big RDG licensees, 1 x 3 years in mammography, interventional radiology, 1 x 4 years in small RDG licensees; dental without regular frequency)

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The Regulatory Body undertakes inspections of medical installations with a multi-disciplinary team

CZ: No

The inspections include assessment of

consistency of practice with licensing conditions CZ: yes

procedures and protocols CZ: partly – based on documentation for license; the clinical procedures and protocols are checked by clinical audit

real –world justification CZ: no – we can't look into patient's documentation. Justification is checked by clinical audit. Advice: out of any reason don't slip through your fingers control on justification – it should be checked both by inspections and clinical audit

and optimisation of exposures CZ: partly – based on optimisation of personnel and QA; the clinical optimisation is checked by clinical audit

equipment QC and QA programmes CZ: yes

staff training CZ: partly – based on training in radiation protection, RPE and MPE, education of other staff is checked by clinical audit