



processing steps, as well as in the final product container during storage, shipment and handling. Biopharmaceuticals are particularly sensitive to temperature changes and/or shaking. Strict storage and handling conditions and timely and effective stability/shelf-life* testing are therefore essential for maintaining product integrity and stability, and hence efficacy and safety.



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issuing decisions on granting a license to perform nuclear activity. The Ordinance also regulates the content of the form for notification of the intent to perform nuclear activities, as well as of the application for the issue of a licence to perform the nuclear activity and the method of keeping the register of nuclear conditions, whereas compliance is established by the decision passed by SONS. Ordinance on special conditions (requirements) for individual activities to be performed by expert organizations which perform activities in the area of nuclear safety regulates these mentioned activities Ordinance on the control of nuclear material and special equipment lays down the list of nuclear materials and special equipment as well as of nuclear activities covered by the system of control of production of special equipment and non-nuclear material, the procedure for notifying the intention to and filing the application for a licence to carry out nuclear activities, and the format and contents of the forms for doing so. This Ordinance also lays down the manner in which nuclear material records are kept, the procedure for notifying the state administration body competent for nuclear safety by the nuclear material user, and the keeping of registers of nuclear activities, nuclear material and special equipment by the state administration body competent for nuclear safety, as well as the form and content of official nuclear safety inspector identification card and badge. Ordinance on conditions for nuclear safety and protection with regard to the sitting, design, construction, use and decommissioning of a facility in which a nuclear activity is performed regulates nuclear safety and protection general and specific conditions for sitting, design, construction, use and decommissioning of a facility in which a nuclear activity is performed. In the presentation the special accent will be given to the new Ordinances, adopted in 2008.

27. NUCLEAR SAFETY REGULATIONS IN THE REPUBLIC OF CROATIA

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Education: Ph.D. at University of Zagreb, 1991; M.S. at University of Zagreb 1981; Graduate at Faculty of Natural Science and mathematics 1975.

Membership: Croatian Nuclear Society, Croatian Chemical Society, Croatian Association for the Radiation Protection, International Zeolite Association Synthesis and dissolution of zeolites (ZA, ZX, SM, ZSM-5), synthesis of harmful substances, physical-chemical characterization of the products using various techniques (X-ray diffraction, particle size analyze, IR spectroscopy, AAS, UV vis. spectroscopy, radioactive tracers, GC-MS), immobilization of dangerous materials in zeolites, use of zeolites for environmental protection, detection of warfare agents.

Field of Professional Interest: Special goods, chemicals, nuclear material; CWC; Precursors for drugs; Legislation on chemicals and on nuclear material; Dual use goods; Weapons of mass destruction; Terrorism; Illicit trafficking of Nuclear Materials.

Based on Nuclear Safety Act (*Official Gazette No. 173/03*) in 2006 State Office for Nuclear Safety (SONS) adopted beside Ordinance on performing nuclear activities (*Official Gazette No. 74/06*) and Ordinance on special conditions for individual activities to be performed by expert organizations which perform activities in the area of nuclear safety (*Official Gazette No. 74/06*) the new Ordinance on the control of nuclear material and special equipment (*Official Gazette No. 15/08*) and Ordinance on conditions for nuclear safety and protection with regard to the sitting, design, construction, use and decommissioning of a facility in which a nuclear activity is to be performed (*Official Gazette No. 71/08*). The Ordinance on performing nuclear activities regulates the procedure of notification of the intent to perform nuclear activities, submitting the application for the issue of a licence to perform nuclear activities, and the procedure for