Health surveillance and fitness for work decision of workers exposed to new chemicals (nanoparticles) and new physical hazards (MSF-MRI) requires an ethical analysis.

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Codes of Ethics
Codes of Ethics

- Codes document the standard according to which the profession can be held accountable
- Codes are used as the basis of self-regulation
- Codes provide a practical guide for solving dilemmas

Weight and Intent of Codes

• The codes can be enforced through the administering of a disciplinary action
• Adoption of “guidelines” or “declaration on ethics” because of fewer implication for enforcement
• The codes do not carry the force of law

The Italian Law
Law and Occupational health surveillance in Italy

• The law dated 1956 (decree 303)
• The law dated 1994 (decree 626) according the 89/391 EU framework directive
• The law dated 2008 (decree 81)
Occupational Health Surveillance

- the EU Framework directive
  - To ensure that workers receive health surveillance appropriate to the health and safety risks they incur at work, measures shall be introduced in accordance with national law and/or practices

- the Italian decree
  - to carry out the medical exams to assess fitness to work,
  - to set up medical records,
  - to provide workers and workers’ representatives with information to clarify the meaning of medical exams
  - to provide workers with information about the results of the medical exams
  - to communicate group results of the exams to workers’ representatives and to elucidate their meaning
  - to prescribe workers medical exams when they believe their complaints are work-related
Functions of the Occupational Physician (art. 25/81/2008)

• Duties of the competent doctor
  – 1. The competent doctor:
    • a  …omissis…
    • b. carries out the health surveillance … with protocols relevant to the nature of the risk and taking into account the most advanced scientific findings
    • c – n …omissis…
Evidence based practice

OHS should supply the following key services:

- Comprehensive services covering medical, psychological and social aspects of work,
- Multidisciplinary services oriented to health risk prevention and health promotion,
- Quality-oriented services founded on sound evidence-based practice
- Services integrated with the core business of the company and cooperating with other services of the enterprise,
- Services based on the principle of participation of workers and employers to positively contribute to both workers’ fitness and to the overall development of the enterprise

ILO Convention n 161, 1985
Assessment of workers’ health

• 3.8 Medical examinations and test should not be carried out as perfunctory routine. **Due consideration should be given to their value and relevance.** They should be governed by a set of principles which include:
  – Selecting appropriate tests which are acceptable to workers
  – Discarding tests that cannot meet requirements with respect to their relevance, specificity and sensitivity
  – Periodically reviewing health surveillance programs as a whole and modifying them in the light of improved working conditions

Technical and ethical guidelines for workers’ health surveillance. ILO, 1998
Functions of the Occupational Physician (art. 39/81/2008)

• Conditions of execution of activities
  – The activities of the competent doctor is carried out according to the principles of occupational health and of the code of ethics of the International Commission of Occupational Health
Functions of the Occupational Health Physician (art. 58/81/2008)

• Violations of the article
  – The violation of the article 25 comma b is punished with the arrest up to 1 month or with the fine from 1,000 to 4500 €
INTERNATIONAL CODE OF ETHICS
FOR OCCUPATIONAL HEALTH PROFESSIONALS

UPDATED 2002

http://www.icohweb.org/core_docs/code_ethics_eng.pdf
The ICOH Code

• The content is structured in 3 parts
  – Basic principles
  – Duties and obligations of occupational health professional
  – Conditions of executions of the functions of occupational health professionals

• It is not easy to be applied in daily practice
Development of a policy and a programme

3. The occupational health professionals must advise the management and the workers on factors at work which may affect workers' health. The risk assessment of occupational hazards must lead to the establishment of an occupational safety and health policy and of a programme of prevention adapted to the needs of undertakings and workplaces. The occupational health professionals must propose such a policy and programme on the basis of scientific and technical knowledge currently available as well as of their knowledge of the work organisation and environment. Occupational health professionals must ensure that they possess the required skill or secure the necessary expertise in order to provide advice on programmes of prevention which should include, as appropriate, measures for monitoring and management of occupational safety and health hazards and, in case of failure, for minimising consequences.
8. The occupational health objectives, methods and procedures of health surveillance must be clearly defined with priority given to adaptation of workplaces to workers who must receive information in this respect. The relevance and validity of these methods and procedures must be assessed. The surveillance must be carried out with the informed consent of the workers. The potentially positive and negative consequences of participation in screening and health surveillance programmes should be discussed as part of the consent process. The health surveillance must be performed by an occupational health professional approved by the competent authority.
Biological monitoring and investigations

12. Biological tests and other investigations must be chosen for their validity and relevance for protection of the health of the worker concerned, with due regard to their sensitivity, their specificity and their predictive value. Occupational health professionals must not use screening tests or investigations which are not reliable or which do not have a sufficient predictive value in relation to the requirements of the work assignment. Where a choice is possible and appropriate, preference must always be given to non-invasive methods and to examinations, which do not involve any danger to the health of the worker concerned. An invasive investigation or an examination which involves a risk to the health of the worker concerned may only be advised after an evaluation of the benefits to the worker and the risks involved. Such an investigation is subject to the worker’s informed consent and must be performed according to the highest professional standards. It cannot be justified for insurance purposes or in relation to insurance claims.
Characteristics of the practice

• Relevance
  – Nature and degree of risk, biological plausibility

• Accuracy
  – Reproducibility, sensitivity, specificity

• Need
  – Relevance of preventive measures

• Consequences
  – Exclusion of workers, social context, privacy

The Occupational Physician meets a problem and takes a decision

Muir Gray JA, Evidence Based Health Care, 2004
## Health surveillance of workers exposed to nanoproducts

### Table 1. Ethical issues pertaining to workplace situations involving nanomaterials.

<table>
<thead>
<tr>
<th>Work-related scenarios</th>
<th>Ethical principles involved</th>
<th>Decisionmaking issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification and communication of hazards and risks</td>
<td>Responsibilities of scientists</td>
<td>Extent to which strengths and weaknesses of data are identified</td>
</tr>
<tr>
<td></td>
<td>Nonmaleficence</td>
<td>Degree of participation in public discussion</td>
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<tr>
<td></td>
<td>Autonomy</td>
<td>Accuracy of communications</td>
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<td></td>
<td>Respect for persons</td>
<td>Timeliness of communications</td>
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<tr>
<td>Workers' acceptance of risks</td>
<td>Autonomy</td>
<td>Extent of inclusion of workers in decisionmaking</td>
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<td></td>
<td>Respect for persons</td>
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<td></td>
<td>Justice</td>
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<tr>
<td>Selection and implementation of workplace controls</td>
<td>Nonmaleficence</td>
<td>Level of control technologies utilized</td>
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<tr>
<td></td>
<td>Beneficence</td>
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<td></td>
<td>Respect for persons</td>
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<tr>
<td>Medical screening of nanotechnology workers</td>
<td>Autonomy</td>
<td>Appropriateness of the rationale for medical screening</td>
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<tr>
<td></td>
<td>Privacy</td>
<td>Extent to which participation is voluntary</td>
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<td></td>
<td>Respect for persons</td>
<td>Maintenance of privacy test results</td>
</tr>
<tr>
<td>Investment in toxicological and control research</td>
<td>Nonmaleficence</td>
<td>Adequacy of investment</td>
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<td>Justice</td>
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<tr>
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<td>Respect for persons</td>
<td></td>
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</tbody>
</table>

Schulte PA, Salamanca-Buentello F. Ethical and Scientific Issues of Nanotechnology in the Workplace. Environmental Health Perspectives, 2007
The link between Evidence and Ethics

• “In the absence of scientific clarity about the potential health effects of occupational exposure to nanoparticles, a need exists for guidance in decision making about hazards, risks, and controls”.

• “An identification of the ethical issues involved may be useful to decision makers, particularly employers, workers, investors, and health authorities”

Schulte PA, Salamanca-Buentello F. Ethical and Scientific Issues of Nanotechnology in the Workplace. Environmental Health Perspectives, 2007
Health Surveillance of Workers exposed to Nanoproducts

• Target organs
  – Respiratory tract
  – Deep lung
  – Dermal penetration
  – Gastrointestinal absorption
  – Eye
  – Cardiovascular system

Schulte PA et al. Options for occupational health surveillance of workers potentially exposed to engineered nanoparticles: State of the science. JOEM;2008;50:517-526
Health Surveillance of Workers exposed to Magnetostatic Fields

Static magnetic fields

The available evidence from epidemiological and laboratory studies is not sufficient to draw any conclusions with regard to chronic and delayed effects. IARC (IARC, 2002) concluded that there was inadequate evidence in humans for the carcinogenicity of static magnetic fields, and no relevant data available from experimental animals. Their carcinogenicity to humans is therefore not at present classifiable.

Short-term exposure to static magnetic fields in the tesla range and associated field gradients induce a number of acute effects.

Cardiovascular responses, such as changes in blood pressure and heart rate, have been occasionally observed in human volunteer and animal studies. However, these were within the range of normal physiology for exposure to static magnetic fields up to 8 T.

Physical movement within a static field gradient induced sensations of vertigo and nausea, and sometimes phosphenes and a metallic taste in the mouth, for static fields in excess of about 2 - 4 T. Although only transient, such effects may adversely affect people. Together with possible effects on eye-hand coordination, the optimal performance of workers executing delicate procedures (e.g. surgeons) could be reduced, with a concomitant impact on safety.
Health Surveillance of well-known and uncertain risks

**Well-known Risks**
- Epidemiological aspects
- Target
- Biological monitoring
- Health examination
- Other measures

**Uncertain Risks**
- Few/anecdotal reports on human toxicity
- Pathophysiological aspects under experimental study
- Exposure and effect indicators
- Health examination

*Schulte PA et al. Options for occupational health surveillance of workers potentially exposed to engineered nanoparticles: State of the science. JOEM;2008;50:517-526
To deal with the legal obligation to undertake an action and with the uncertainties related to nanoparticles and MSF

- No relevant, scientifically sound and knowledge based practice is available for recommending medical screening of the exposure
- The validity of non-specific medical examination may be questioned
  - The health end point to be measured are not known
  - Non specific health examination may identify effect unrelated to the exposure
- The problem of false positives
- The availability of baseline data of workers’ group for time series comparison
The Ethical Analysis of Dilemmas

• The approach proposed by Westerholm, Nilstun and Ovretveit, 2004

  – The **stakeholders**
    • Employer, Management, OHS, Workers’ representative, Union, Insurance company, Inspection agency, Community
  
  – The **ethical principles**
    • The ethical benefits and the ethical costs
Ethical principles

• **Beneficence and non-maleficence**
  - meaning that actions are taken in order to maximize benefits to individuals and society. It is the principle of doing good
  - actions should not harm others. It is derived from the Hippocratic "first, do no harm."

• **Autonomy** (respect for)
  - This is the principle of allowing people to make decisions about themselves for themselves.
  - It is related to respecting human dignity, believing in a person's ability to make good decisions and is the opposite of paternalism.

• **Justice**
  - This refers to distributive justice and is the principle requiring that benefits and harms should be equally distributed among people.
  - It is related ideas are fairness, equity and impartiality.

Westerholm P et al, 2004
# PROFESSIONAL ETHICS

Table 1.

<table>
<thead>
<tr>
<th>Persons involved or affected</th>
<th>Ethical principles</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Beneficence</td>
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<tr>
<td>Employees</td>
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<tr>
<td>Employer/management</td>
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<tr>
<td>The OH professional</td>
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<td>Staff of OH service</td>
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</table>

Is it possible to grade cost and benefits? A practical exercise
A tentative to grading cost and benefit by the ethical analyses

<table>
<thead>
<tr>
<th></th>
<th>Worker</th>
<th>Employer</th>
<th>OP</th>
<th>Community</th>
<th>Delegate</th>
<th>Inspection</th>
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<td><strong>Beneficence</strong></td>
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<td>1</td>
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<tr>
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<td>1</td>
<td>2</td>
<td>1</td>
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<td><strong>Autonomy</strong></td>
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</tbody>
</table>

The document is published at http://docs.google.com/Doc?id=d5272nd_0d49p48hk&hl=it
According to the principles of beneficience/not maleficience

• **Ethical costs**
  - no specific tests exist
  - difficulties of interpreting the results of generic surveillance
  - lack of criteria for fitness for work
  - worker’s perception of false sense of safety
  - psychological stress after false positive results

• **Ethical benefits**
  - knowledge of the health condition, which makes it possible to suspect adverse effects
According to the principle of autonomy

- Ethical costs
  - obligation for the worker to be examined
According to the principle of justice

- Ethical costs
  - a violation of the privacy exists when the worker is judged unfit for work and this information is made available to the employer.
How should the OP face the Dilemma?

- To take an action?
- Which action?
- To do nothing?
- To inform about the uncertainties?
- Who should be informed?
- To adopt a precautionary approach?
An approach which is gaining widespread support is the precautionary principle. Simply stated, it is the need to foresee and forestall damaging human activities before science delivers irrefutable proof that there is a problem. We have seen many examples where concerns have been raised about a substance or process, to be told that there is no proof that it is harmful. By the time proof is established, hundreds, if not thousands, of people may have died, or suffered irreversible damage to their health.

When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. This is articulated in four clauses:

- people have a duty to take anticipatory action to prevent harm;
- the burden of proof of harmlessness of a new technology, process, activity or chemical lies with the activity’s proponents, not with the general public;
- before using a new technology, process or chemical, or starting a new activity, people have an obligation to examine a full range of alternatives, including the alternative of doing nothing; and
- decisions applying the precautionary principle must be open, informed and democratic, and must include affected parties.
Conclusion

• No definitive answer for appropriately comply with the new Italian law

• The method for analyzing ethical aspects may be adopted as a tool for undertaking ethically-based actions by the OP
Health surveillance and fitness for work decision of workers exposed to new chemicals (nanoparticles) and new physical hazards (MSF-MRI) requires an ethical analysis.