

**COMMENTS ON NIOSH CURRENT INTELLIGENCE BULLETIN, OCCUPATIONAL EXPOSURE TO CARBON NANOTUBES AND NANOFIBRES
NIOSH 161-A**

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This document presents one of the first credible attempts to provide an evidence based exposure limit for carbon nanotubes. This is a difficult and challenging task given the many variations of carbon nanotubes which have been described in the literature, the limited evidence available in relation to potential exposure for these types of materials, the lack of any agreed measurement methods for estimating exposure to these materials, the limited information available in relation to the hazardous nature of these materials, and widely described issues in the literature relating to the appropriate choice of metric by which exposure to these materials should be addressed (accessed). However, in a general sense the document is well balanced, proportionate and pragmatic document which does draw together the key and important elements of the evidence across the range of the risk issues associated with potential exposure to CNTs. In relation to the exposure situations described, and the health effects used as the basis of the derivation of the limit, NIOSH have identified all of the appropriate and relevant studies which could be used to come to the conclusions that they have come to.

However, there are some important issues that need to be further considered.

It has been widely discussed in the literature, the potential similarities between some types of carbon nanotubes and asbestos. The similarities based on what is known as the "fibre paradigm". That is that long durable bio-persistent fibres, such as asbestos, if inhaled, have the potential to enter the plural space in which they are retained and in due course can give rise in the development of mesothelioma. Elements of the fibre paradigm have been demonstrated with some types of carbon nanotubes. For example Poland *et al* (2008) have shown a length dependent effect associated with the development of inflammation for carbon nanotubes injected directly into the peritoneal cavity of a mouse. Osmond *et al* (in press) have compared the durability of CNT as compared with asbestos fibres. Many other papers and reports have speculated on the potential association (e.g. Maynard *et al* 2006).

It appears that NIOSH have not considered this potential health effect in deriving their exposure limits. Rather they have focused on the health effects of pulmonary fibrous and granulomatous inflammation. To some extent this is justified. These effects (as described in the quoted studies in the document) are ones for which inhalation studies are available which provide the basis for establishment of a dose response relationship and therefore the establishment of an occupational exposure limit. Whilst they have generalised these studies for all carbon nanotube types (including single and multiple for example) it is recognised that only some (perhaps limited number) of carbon nanotube types are actually likely to or provide the possibility of generating aerosol releases that may be considered to be fibres (according to the WHO definition). It therefore makes some sense to develop a limit based on the evidence which is available, rather than for a small sub category of materials, for which there is not at all clear whether or not there will ever be exposure. However there are two dangers in this approach. Firstly, if carbon nanotubes can be released in a form that makes them consistent with long durable fibres such as those evaluated in the Poland study and if exposure to these occurs then it is highly likely that the recommended exposure limits produced by NIOSH will not be at all protective to those who are exposed at that level. To be clear, an exposure

limit based on the fibre paradigm would result in a level that maybe several orders of magnitude below that currently being recommended by NIOSH. This clearly provides a cause for concern.

Given the knowledge and the prevalence of the discussions relating to this potential fibre paradigm issue for carbon nanotubes, and given that there is no clear statement within the current document that this is NOT the basis on which the limit has been developed, it is quite conceivable that people who use this document but who do not clearly read or carefully understand the basis for the derivation of the proposed limit will expect that the limit value produced will be protective for CNTs of the types which can be released as fibres. To some extent this issue could be resolved with some clear statements which indicated what health effect the limit is derived on but making specific reference to the fibre paradigm and indicating that this is NOT the basis for which the limit has been derived.

NIOSH (on page 42) note that the REL that derived may not be completely health protective. In fact they indicate that the animal data-based risk estimates indicate that workers may have a greater than 10% excess risk of developing early stage pulmonary fibrosis if exposed over a full working life time at this value. The value is chosen as it is the limit of quantitation (LOQ) of NIOSH method 5040 which is currently the recommended analytical method for measuring airborne CNT.

I am not sufficiently familiar with NIOSH's approach in relation to these to say whether these are standard approach or not but I do not believe that greater than 10% excess risk is the normal criteria which NIOSH or indeed other limit setting organisations would choose. It would be very helpful that within this document a REL calculated according to the usual criteria was to be produced even if at the current time analytical methods were not available by which this could be measured. It could be further recognised more clearly that this proposed limit is only one based on analytical methods and that more data and indeed better methods are required in order to control exposure to a limit at which the excess risk is acceptable.

Further discussions of this issue and the clear statement about the limitations of the methods would be beneficial, as would the encouragement to develop new protection methods which would allow detection at lower levels. Whether method 5040 will be the most appropriate, long term, remains to be seen.

In conclusion, NIOSH are to be congratulated for producing such a clear and well thought out document. My concern is, for the reasons described above, the limit value proposed will not be sufficiently protective for some types of CNT and will not prevent instances of disease in population which are exposed to carbon nanotubes.

References

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